# ORIGINAL

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

COUNTY OF SUFFOLK,

Plaintiff.

v.

ABBOTT LABORATORIES, INC., AGOURON PHARMACEUTICALS, INC., AMGEN, INC., ASTRAZENECA PHARMACEUTICALS L.P., ASTRAZENECA US, AVENTIS BEHRING, AVENTIS PHARMACEUTICALS INC., BARR LABORATORIES, INC., BAYER AG, BERLEX LABORATORIES, INC., BIOGEN, INC., BRISTOL-MYERS SQUIBB COMPANY, ELI LILLY AND COMPANY, FUJISAWA PHARMACEUTICAL COMPANY, LTD., GENENTECH, INC., GLAXO WELLCOME, P.L.C., GLAXOSMITHKLINE PLC, IMMUNEX CORPORATION, IVAX CORPORATION, IVAX PHARMACEUTICALS INC., JANSSEN PHARMACEUTICAL, JOHNSON & JOHNSON, MEDIMMUNE, INC., MERCK & CO., INC., NOVARTIS PHARMACEUTICALS CORPORATION, ORTHO BIOTECH, ORTHO MCNEIL PHARMACEUTICALS, PFIZER INC., PHARMACIA CORPORATION, PURDUE PHARMA, L.P., RELIANT PHARMECEUTICALS, SANOFI-SYNTHELABO, INC., SCHERING-PLOUGH CORP., SMITHKLINEBEECHAM P.L.C, TAP PHARMACEUTICALS, WARRICK PHARMACEUTICALS, WYETH, and DOES 1-100

Defendants.

MDL. NO. 1456

JUDGE PATTI SARIS

03-10643-PBS

AMENDED COMPLAINT

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Plaintiff, the County of Suffolk (hereinafter "Suffolk"), brings this action under the Racketeering Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 et seq, the Social Security Act, 42 U.S.C. §1396r-8, New York Social Services Law §§367 and 145-b, New York General Business Law §349, and common law to recover monetary damages, civil penalties, declaratory and injunctive relief, restitution, disgorgement of profits, treble and punitive damages suffered as a result of defendants' unlawful scheme to overcharge for prescription medications paid for by Medicaid. Suffolk County is required by New York State law to pay 25% of its Medicaid costs, including the cost of prescription drugs ("pharmacy costs"). Suffolk County is also required to balance its budget annually. Every dollar wrongfully spent on Medicaid could have properly been allotted to other public needs. Suffolk's claims as to itself and its own actions are based upon its personal knowledge. All other allegations are based upon information and belief pursuant to the investigation of counsel.

#### I. INTRODUCTION

- 1. Each of the defendants is or has been engaged in the business of manufacturing, marketing and selling prescription pharmaceuticals throughout the United States. The principal payors for such prescription pharmaceuticals are federal, state and local governments (under the Medicare and Medicaid Programs), private insurers and self-insured employers (Third-Party Payors), and private individuals (Patients). Plaintiff is a municipal corporation and local government required by New York State law to contribute 25% towards its Medicaid costs.
- 2. For the last decade, defendants have engaged in a systematic and pervasive fraudulent scheme with others in the pharmaceutical distribution chain, including but not limited to pharmacies, physicians, hospitals and other medical providers (hereinafter "providers"), to collect inflated prescription drug payments from Suffolk. The scheme generally involves two types of wrongdoing, one of which impacts the other. First, the fraudulent reporting of false and inflated

average wholesale prices ("AWPs") (or wholesale acquisition costs ("WACs) on which AWPs are based) for certain drugs. Second, the failure to report the "Best Price" for certain drugs in violation of federal and state Medicaid statutory requirements, which failure also inflates AWP.

- 3. It is standard practice that for federal Medicare and Medicaid Programs, state and local Medicaid entities (such as Suffolk), Third Party Payors and patients reimburse providers for multi source (generic) and brand name prescription drugs for which there is no "Federal Upper Limit" based upon the AWP for such drugs, as published and reported by third-party reporting services such as the Blue Book, Medispan or RedBook.
- 4. Suffolk pays for most prescription drugs based on AWP pursuant to federal and state statute and regulation. Because defendants artificially inflate the AWP in order to manipulate reimbursements, plaintiff has made excessive payments. As set forth in Exhibit A hereto, defendants have reported false and inflated AWPs for every Medicaid Covered Drugs paid for by Suffolk. The improper inflation rates range up to 69% This practice has resulted in millions of dollars in overcharges to Suffolk County.
- 5. The inflationary scheme is successful in part because Pharmaceutical companies either self-report an inflated AWP to publishers which then publish the AWP provided to them, or self-report an inflated WACs which the publisher then converts to AWP. In either case, the AWP is not independently determined by the publishers.
- 6. By federal and state statute and regulation, and industry practice, the AWP is intended and required to be based upon and directly related to actual prices paid by providers to pharmaceutical manufactures (or wholesalers) for such prescription drugs.
- 7. In fact, as has been revealed by Suffolk's own investigation (See Exhibit A) and extensive and ongoing Congressional and federal investigations, and numerous recent

settlements involving many of the defendants herein, pharmaceutical manufacturers have engaged in a pervasive scheme, commencing in 1993 if not earlier, whereby they report or cause to be reported, fraudulent, fictitious and inflated AWPs or WACs for certain prescription pharmaceuticals, including prescription pharmaceuticals paid for by Medicaid and thus by Suffolk.

- 8. The fraudulent AWP Scheme described herein also has involved the affirmative failure of defendants to report their Best Prices as required by federal and state Medicaid statute, thereby further inflating the reported AWPs. Pursuant to 42 U.S.C. § 1396r-8, each of the defendants was required to report to the Secretary of Health and Human Services the lowest price it sold a drug to any for-profit entity. Each defendant agreed to offer the Medicaid Program its "best price." A like requirement appears in New York State's Medicaid Statute. See New York Social Services Law § 367-(a)(7)(d). Yet, defendants exclude from their reporting of best prices certain drugs offered at discounts or other rebates that would have reduced the price paid. They do so to avoid paying rebates to Medicaid and to avoid having to disclose the true best price, which would have required a reduction in the reported AWP.
- 9. The fraudulent reporting of Average Wholesale Prices has the effect of materially misrepresenting and overstating the true AWP on which reimbursement should be based.
- 10. The motivations for the scheme is straight-forward. By inflating the AWP in which Medicaid reimbursement is based, defendants motivate providers to distribute the drugs with the highest reimbursement rate. This practice is known as "marketing the spread." Providers benefit by pocketing the difference between the reported AWP and the actual cost paid for the drug.
- 11. This scheme is not a matter of speculation. Defendant Bayer recently paid \$260 million in civil and criminal fines in connection with allegations that they failed to report Best Prices for certain drugs thereby resulting in overcharges to Medicaid and Medicare. Defendant

GlaxoSmithKline recently paid \$88 million to resolve civil charges that it caused Medicaid and Medicare to overpay for certain drugs. Defendant Abbott is paying \$621 million in criminal and civil penalties for defrauding Medicare and Medicaid and has affirmatively acknowledged its involvement in the fraud. Defendant Bristol Myers is under investigation in connection with its pricing practices for drugs covered by Medicare and Medicaid. Defendant AstraZeneca paid \$355 million to settle federal fraud charges that it induced doctors to falsely bill Medicare and Medicaid. Defendant Pfizer paid \$49 million for failure to disclose discounts and properly report best prices for a certain drug. Defendant Schering-Plough faces threat of indictment for cheating the government out of Medicaid rebates and submitting false price information. Defendant TAP Pharmaceuticals paid \$875 million in connection with its fraudulent pricing practices respecting Lupron.

- 12. The foregoing settlements, the government investigations that prompted them, and the corporate integrity agreements executed by the settling companies are discussed herein. Certain of the settlements may impact a portion of Suffolk's damages for certain years with respect to certain drugs. In any event, the settlements and compliance agreements executed by the settling parties confirm the allegations of wrongdoing herein.
- 13. Even as to the defendants not mentioned above, Suffolk's initial research confirms that the practice of routinely and systematically inflating the reported AWPs for certain drugs and failing to report Best Prices is pervasive. See Exhibit A. Indeed, defendants must participate lockstep in the fraud to prevent dispensers such as pharmacies and doctors from prescribing drugs of a competitor with a higher spread between Medicaid reimbursement rate and direct price.
  - 14. In brief summary, the fraudulent scheme devised and initiated by defendants

and implemented by its co-conspirators (DOES 1-100) is effectuated by: (i) overstating the AWP for drugs for which Medicaid provides reimbursement based upon AWP ("Covered Drugs");(ii) marketing and promoting the sale of Covered Drugs to providers based on the providers' ability to collect inflated payments from the government and Medicaid beneficiaries that exceeded payments possible for competing drugs; (iii) providing providers with unreported discounts free samples and financial incentives to over-prescribe Covered Drugs or prescribe Covered Drugs in place of competing drugs; and (iv) overcharging the Medicaid program for illegally inflated Covered Drugs reimbursements.

15. According to one member of the Congressional Ways and Means Committee, describing the conduct of one defendant herein:

The price manipulation scheme is executed through Bristol's falsely inflated representations of average wholesale price ("AWP"), direct price ("DP"), and wholesale acquisition cost ("WAC"), which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP, DP, and WAC versus the true price providers are paying, is regularly referred to . . . as "the spread."

\* \* \*

The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

(February 27, 2001 letter from Representative Pete Stark to Peter Dolar, President, Bristol-Myers Squibb Co.).

16. Suffolk alleges upon information and belief that, in many instances, the AWP reported by the defendant pharmaceutical manufacturers bears a minimal relationship to the prices

actually paid by providers and is "made up" by corporate pricing committees literally out of "thin air" for the purpose of manipulating pharmaceutical markets and increasing market share. Many of the facts underlying this fraud, such as the volume and nature of the discounts provided and free samples distributed, are peculiarly within defendants' control.

- 17. Thus, defendants knowingly have violated federal and state statutes by deliberately publishing false, inflated and misleading price data that directly results in excessive payments by Suffolk. Neither federal nor state statutory schemes, even to the extent they base reimbursement on AWPs, permit defendants to engage in this widespread, concerted fraud. Suffolk would not have been damaged if defendants complied with the existing federal and state laws.
- 18. As a result of the fraudulent and illegal manipulation of AWP for covered drugs by defendants, defendants have reaped billions of dollars in illegal profits at the expense of American consumers, taxpayers and entities such as plaintiff that make pay reimbursements for Medicaid pharmacy costs.

#### II. JURISDICTION AND VENUE

- 19. This action is brought for and on behalf of the County of Suffolk, pursuant to, *inter alia*, the Racketeering Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq*, New York's Social Services Law §§ 145-b and 367a, New York's Consumer Protection Statute, Gen. Bus. Law § 349, and for breach of contract, unjust enrichment, and common law fraud.
- 20. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because the action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, et seq. and the Social Security Act, 42 U.S.C. § 1396 et seq. This Court has supplemental jurisdiction over plaintiff's state law claims pursuant to 28 U.S.C. § 1367.
  - 21. Venue is proper in this District because this matter was transferred here for

pre-trial purposes pursuant to 28 U.S.C. § 1407, by order dated March 3, 2003. This matter originally was filed in the Eastern District of New York where venue was proper pursuant to 28 U.S.C. §§ 1391(b) and (c) because defendants do business and are qualified to do business in that District; certain acts giving rise to the claims asserted in this Complaint occurred within that District; and the illegal actions of defendants, as alleged in this Complaint, caused damage to plaintiff within that District.

#### III. PARTIES

- 22. Plaintiff, the County of Suffolk, New York is and was at all relevant times, a body corporate and politic organized and existing under the laws of the State of New York with its principal place of business located at the County Complex, Veterans Memorial Highway, Hauppauge, New York.
- 23. Defendant Abbott Laboratories, Inc. ("Abbott") is a highly diversified Illinois corporation whose principal business is the development, manufacture, and sale of health care products and services, including pharmaceuticals. Abbott's principal place of business is at 100 Abbott Park Road, Abbott Park, Illinois. Abbott conducts extensive business in the State of New York, including in the County of Suffolk. Abbott manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Depakote® and Kaletra®.
- 24. Defendant Agouron Pharmaceuticals Inc. ("Agouron") is a California corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals and a wholly owned subsidiary of Pfizer. Agouron's principal place of business is 10350 North Torrey Pines Road, Suite 100 La Jolla, California 92037. Agouron does extensive business in the State of New York, including in the County of Suffolk. Agouron manufactures and sells prescription drugs with false and inflated AWPs that are paid for

by Medicaid in Suffolk County, including such medications as Viracept®.

- 25. Defendant Amgen, Inc. ("Amgen") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Amgen's principal place of business is One Amgen Drive, Thousand Oaks, California. Amgen does extensive business in the State of New York, including in the County of Suffolk. Amgen manufactures and/or sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Neuprogen®, Enbrel® and Epogen®.
- Defendant AstraZeneca Pharmaceuticals L.P. (collectively referred to as "AstraZeneca") are Delaware corporations whose principal businesses are the development, manufacture and sale of health care products including pharmaceuticals. AstraZeneca's principal place of business is at 1800 Concord Pike, Wilmington, Delaware. AstraZeneca does extensive business in the State of New York, including in the County of Suffolk. AstraZeneca manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Nexium®, Prilosec® and Seroquel®.
- 27. Two wholly-owned subsidiaries of French-domiciled Aventis S.A., Defendant Aventis Behring L.L.C. and Defendant Aventis Pharmaceuticals Inc., (collectively referred to as "Aventis") are located in the US. Defendant Aventis Behring is located at 1020 First Avenue, King of Prussia, Pennsylvania 19406. Defendant Aventis Pharmaceuticals Inc. is located at 300-400 Somerset Corporate Boulevard, Bridgewater New Jersey. Aventis Behring formerly did business as Centeon L.L.C., a joint venture between Rhone-Poulenc Rorer, S.A. and Hoechst Marion Roussel, Inc. ("Hoechst"). Aventis manufactures, markets and sells prescription drugs with

false and inflated AWPs that are paid for by Medicaid of Suffolk County, including such medications as Helixate FS®.

- 28. Defendant Barr Laboratories, Inc. ("Barr") is a specialty pharmaceutical company primarily engaged in the development, manufacture and marketing of generic and proprietary prescription pharmaceuticals. Its business address is 2 Quaker Road Box 2900 Pomona, NY 10970-0519. Barr conducts extensive business in the State of New York, including in the County of Suffolk. Barr manufactures and/or sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Fluoxetine®.
- 29. Defendant Bayer Corporation ("Bayer") is an Indiana corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Bayer's principal place of business is located at 100 Bayer Road, Pittsburgh PA. Bayer's pharmaceutical division is located at 400 Morgan Lane, West Haven, Connecticut. Bayer conducts extensive business in the State of New York, including in the County of Suffolk. Bayer is a wholly owned US subsidiary of a German corporation, Bayer AG. Bayer manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Cipro®.
- 30. Defendant Berlex Laboratories, Inc. ("Berlex") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products, including pharmaceuticals. Berlex's principal place of business is P.O. Box 1000, Montville, New Jersey 07045-1000. Berlex conducts extensive business in the State of New York, including in the County of Suffolk. Berlex Laboratories manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Betaseron®.

- 31. Defendant Biogen, Inc. ("Biogen") is a highly diversified health care company whose principal business is the development, manufacture and sale of health care products, including pharmaceuticals. Biogen's principal place of business is 14 Cambridge Center, Cambridge, Massachusetts 02142. Biogen conducts extensive business in the State of New York, including in the County of Suffolk. Biogen manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Avonex®.
- 32. Defendant Bristol-Myers Squibb Company ("Bristol-Myers") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products, including pharmaceuticals. Bristol-Myers's principal place of business is 345 Park Avenue, New York, New York. Bristol-Myers does extensive business in the State of New York, including in the County of Suffolk. Bristol-Myers manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Glucophage®, Sustiva®, Pravachol®, Buspar®, and Plavix®.
- 33. Defendant Chiron Corporation's ("Chiron") principal business is the development, manufacture and sale of health care products including pharmaceuticals. Chiron's principal place of business is 4560 Horton Street, Emeryville, CA 94608-2916. Chiron conducts extensive business in the State of New York, including in the County of Westchester. Chiron manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Tobi®.
- 34. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Lilly does extensive business in the State of New York, including in the

County of Suffolk. Lilly manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Zyprexa®, and Prozac®.

- 35. Defendant Forest Pharmaceuticals Inc. ("Forest") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Forest's principal place of business is 13600 Shoreline Drive, St. Louis, Missouri 63045. Forest conducts extensive business in the State of New York, including in the County of Westchester. Forest manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Celexa®.
- 36. Defendant Fujisawa Healthcare, Inc. ("Fujisawa") is a Delaware corporation headquartered at Three Parkway North, Deerfield, IL, 60015. Fujisawa is a wholly-owned subsidiary of Fujisawa Pharmaceutical Co., Ltd., a Japanese corporation. Fujisawa conducts extensive business in the State of New York, including in the County of Suffolk. Fujisawa manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Prograf®.
- 37. Defendant Genentech, Inc. ("Genentech") is a Delaware corporation whose principal business is the discovery, development, manufacture, and sale of pharmaceuticals. Genentech's principal place of business is One DNA Way, South San Francisco, CA. Genentech conducts extensive business in the State of New York, including in the County of Suffolk. Genentech manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Pulmozyme®.
- 38. The GSK Defendants. (a) Defendant GlaxoSmithKline P.L.C. ("GSK") is a research-based pharmaceutical and healthcare public limited company incorporated under the

laws of England and Wales that is engaged in the creation and discovery, development, manufacture and marketing of pharmaceutical products, vaccines, over-the-counter medicines and health-related consumer products. Its corporate headquarters are located at 980 Great West Road, Bretford, Middlesex, EN, TW8 9, U.K. GSK's United States operational headquarters are at One Franklin Plaza, Philadelphia, PA 19102. GSK also does business at 5 Moore Drive, P.O. Box 13398, Research Triangle Park, North Carolina. GSK does extensive business in the State of New York, including in the County of Suffolk.

- (b) GSK was created through the merger of defendant Glaxo Wellcome, P.L.C. ("Glaxo") and defendant SmithKlineBeecham P.L.C ("SKB P.L.C."). Both Glaxo and SKB P.L.C. are now wholly-owned subsidiaries of GSK.
- (c) SKB P.L.C. owned defendant SmithKline Beecham Corporation ("SKB"). SKB is a Pennsylvania corporation with its principal place of business at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania. SKB is a highly diversified health care company whose principal business is the development, manufacture and sale of health care products and services, including pharmaceuticals.
- (d) Glaxo and SKB at certain times relevant to this complaint, conducted extensive business in the County of Suffolk including the sale of the pharmaceuticals that are the subject of the AWP Scheme alleged herein.
- (e) Glaxo is a North Carolina corporation with its principal place of business at 5 Moore Drive, P.O. Box 13398, Research Triangle Park, North Carolina.
- (f) Defendants GSK and Glaxo collectively referred to herein as the "GSK Defendants" manufacture and/or sell prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County. Glaxo and GSK manufacture and or sell prescription

drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Epivir® and Wellbutrin®, Lamictal®, Serevent®, Paxil®, Augmentin®, Avandia®, Ziagen®, Flovent®, Flonase®.

- 39. Defendant Immunex Corporation ("Immunex") is a Washington State corporation, with its principal place of business at 51 University Street, Seattle, Washington, that was acquired by Amgen in July 2002, and has been a wholly-owned subsidiary since this merger. Immunex does business in the State of New York, including the County of Suffolk. Immunex manufactures prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including Enbrel® which is marketed and sold by Amgen and Wyeth.
- 40. Defendant Ivax Corp. is a Florida corporation engaged in the research, development, manufacture and marketing of pharmaceutical products. Its principal place of business is 4400 Biscayne Blvd., Miami, FL, 33137. Ivax Corp. is the corporate parent of defendant Ivax Pharmaceuticals Inc. Ivax manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Clozapine®.
- 41. The Johnson & Johnson Defendants. (a) Defendant Johnson & Johnson ("J&J") is a New Jersey corporation engaged in the manufacture and sale of a broad range of products in the healthcare field. Its principal place of business is One Johnson & Johnson Plaza, New Brunswick, NJ, 08933. Johnson & Johnson is the corporate parent of defendants Janssen Pharmaceutical, Ortho McNeil, and Ortho Biotech and is responsible for the marketing and distribution of its subsidiaries' drugs, which have false and inflated AWPs as set forth herein. The four Defendants are at times referred to collectively herein as "the J&J Defendants."

- (b) Defendant Janssen Pharmaceutical Products ("Janssen") is a New Jersey limited partnership whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Janssen's principal place of business is 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Janssen is subsidiary of defendant Johnson and Johnson. Janssen conducts extensive business in the State of New York, including in the County of Suffolk. Janssen manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Risperdal® and Duragesic®.
- (c) Defendant Ortho McNeil Pharmaceuticals ("Ortho McNeil") is a highly diversified health care company incorporated in New Jersey whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Ortho McNeil's principal place of business is1000 U.S. Route 202 South, Raritan, New Jersey 08869. Ortho McNeil conducts extensive business in the State of New York, including in the County of Suffolk. Ortho McNeil manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Levaquin®, Topamax® and Ultram®.
- (d) Defendant Ortho Biotech is a New Jersey Corporation and has been a wholly owned subsidiary of defendant Johnson and Johnson since its formation in 1990. Ortho Biotech's principal place of business is located at 700 U.S. Highway 202, Raritan, New Jersey. Ortho Biotech manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Procrit®.
- 42. Defendant MedImmune, Inc. ("MedImmune") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products

including pharmaceuticals. MedImmune conducts extensive business in the State of New York, including in the County of Suffolk. MedImmune's principal place of business is 35 W. Watkins Mill Road, Gaithersburg, Maryland 20878. MedImmune manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Synagis®.

- 43. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Merck's principal place of business is One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey 08889-0100. Merck conducts extensive business in the State of New York, including in the County of Suffolk. Merck manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Crixivan®, Vioxx®, Zocor®, Singulair®, and Fosamax®.
- Jersey Corporation with its main place of business at One Health Plaza, East Hanover, New Jersey. Novartis is a U.S. affiliate of Novartis AG. Novartis is a highly diversified health care corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Novartis conducts extensive business in the State of New York, including in the County of Suffolk. Novartis manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Clozaril®.
- 45. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation whose principal business was the development, manufacture and sale of health care products including pharmaceuticals. Pfizer's principal place of business is 235 East 42nd Street, New York, New York

- 10017. Pfizer does extensive business in the State of New York, including in the County of Suffolk. Pfizer manufactures and/or sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Ambien®, Lipitor®, Neurontin®, Norvasc®, Zoloft®, Zyrtec®.
- 46. Defendant Pharmacia Corporation ("Pharmacia"), which became a wholly owned subsidiary of Pfizer on April 16, 2003, is a Delaware corporation with its principal place of business located at 100 Route 206, North Peapack, New Jersey. Pharmacia was created through the merger of Defendant Pharmacia and Upjohn, Inc. and Monsanto Company on March 31, 2000. Pharmacia is a highly diversified health care company whose business includes the manufacture and sale of prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Celebrex® and Xalatan®.
- 47. Defendant Purdue Pharma, L.P. ("Purdue") is a pharmaceutical company whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Purdue's principal place of business is One Stamford Forum, 201 Tresser Boulevard, Stamford, CT. Purdue conducts extensive business in the State of New York, including in the County of Suffolk. Purdue manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Oxycontin®.
- 48. Defendant Reliant Pharmaceuticals ("Reliant") is based in New Jersey with its principal place of business at 721 Route 202/206 South Bridgewater, NJ, 08807. Reliant manufactures and sells drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County such as Axid®.
  - 49. Defendant Sanofi-Synthelabo, Inc. ("Sanofi") is a highly diversified health

care corporation whose principal business was the development, manufacture and sale of health care products including pharmaceuticals. Sanofi's principal place of business is One Well Street, New York, New York 10286. Sanofi conducts extensive business in the State of New York, including in the County of Suffolk. Sanofi manufactures and /or sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Plavix® and Ambien®.

- 50. Defendant Schering-Plough Corp. ("Schering") is a highly diversified health care corporation whose principal business was the development, manufacture and sale of health care products including pharmaceuticals. Schering is a New Jersey corporation, whose headquarters are located at 2000 Galloping Hill Rd., Kenilworth, New Jersey. Schering-Plough does extensive business in the State of New York, including in the County of Suffolk. Schering, directly or through its subsidiary Warrick, manufactures and/or sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County including Claritin® and Albuterol®
- 51. Defendant TAP Pharmaceutical Products, Inc. ("TAP") is a highly diversified health care company whose principal business was the development, manufacture, marketing and sale of health care products including pharmaceuticals. TAP is a joint venture between Defendant Abbott and Takeda Chemical Industries, Ltd., of Osaka, Japan. TAP conducts extensive business in the State of New York, including in the County of Suffolk. TAP's principal place of business is 675 North Field Drive, Lake Forest, Illinois 60045. Prior to April, 2000, TAP was known as TAP Holdings, Inc. TAP, together with its subsidiary Tap Pharmaceuticals, Inc., manufactures and/or sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Prevacid®.

- 52. Defendant Warrick Pharmaceuticals Corporation ("Warrick") is a Delaware corporation with its principal place of business at 12125 Moya Boulevard, Reno, Nevada. Warrick is a wholly-owned subsidiary of Defendant Schering-Plough and has been since its formation in 1993. Schering-Plough and Warrick manufacture and/or sell prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County including such medications as Claritin® and Albuterol®.
- 53. Defendant Wyeth is a highly diversified health care corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Wyeth is a Delaware corporation whose principal place of business is Five Giralda Farms, Madison, NJ. Wyeth conducts extensive business in the State of New York, including in the County of Suffolk. Wyeth manufactures and/or sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Effexor XR® and Protonix®.

#### AS YET UNNAMED CO-CONSPIRATORS AND DOE DEFENDANTS

- 54. Various other individuals, partnerships, sole proprietors, business entities, companies, and corporations, presently unknown to Suffolk and not named as defendants in this Complaint, participated as co-conspirators in the violations alleged in this Complaint and performed acts and made statements in furtherance thereof. Such unknown persons or entities acted as co-conspirators and aided, abetted, or participated with defendants in the commission of the wrongful acts alleged herein or otherwise caused the damages suffered by Suffolk.
- 55. Except as described herein, plaintiff is, as yet, ignorant of the true names, capacities, nature and extent of the participation in the course of conduct alleged herein of the persons sued as DOES 1-100 inclusive and, therefore, sues these defendants by such fictitious names. Suffolk will amend this Complaint to allege the true names and capacities of the Doe

defendants when ascertained.

- 56. Defendants unknown at this time may include independent pharmacies, dispensers, and other medical providers who prescribed drugs and received inflated Medicaid reimbursements and engaged in fraudulent billing practices, as well as various other persons, partnerships, sole proprietors, firms, corporations and individuals that may have participated as co-conspirators with defendants in the offenses alleged in this complaint and may have performed acts and made statements in furtherance of the alleged illegal conduct.
- 57. Each of the defendants designated herein as a Doe defendant is legally responsible in some manner for the unlawful acts referred to herein. Plaintiff will seek leave of Court if necessary to amend this Complaint to reflect the true names and capacities of the defendants designated herein as Does when such identities become known.

#### IV. GENERAL ALLEGATIONS

58. The allegations contained herein apply generally to all defendants.

#### A. THE AWP SYSTEM

- 59. There are approximately 65,000 different drug products in the United States market, including different dosages of the same drug. Prescription drugs are dispensed to patients by or through different types of medical providers, including but not limited to: (a) physicians who administer the drug in an office, (b) retail pharmacies, (c) home infusion pharmacies, and (d) other medical providers, including hospitals (collectively referred to hereinafter as "providers").
- 60. This case concerns "Covered Drugs", which are those drugs for which, pursuant to N.Y. Soc. Serv. Law § 367-a(9), Suffolk's Medicaid pharmacy cost reimbursement rate is pegged to AWP. In New York's statutory scheme, AWP is also known as "Estimated Acquisition Cost" or "EAC."
  - 61. Providers regularly submit claims for reimbursement, seeking payment for

the drugs from Medicare, Medicaid, insurers and patients. At all times relevant hereto, defendants knew that the Medicare/Medicaid programs rely on published AWPs to reimburse providers for drugs.

- 62. AWPs are published for each drug identified by a National Drug Code ("NDC"). There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWPs for the tens of thousands of drugs. Medical Economics Company Inc. publishes the Drug Topics RedBook (the "RedBook"). First Data Bank compiles the National Drug Datafile. There is also the American Druggist First Databank Annual Director of Pharmaceuticals and Essential Director of Pharmaceuticals (the "Blue Book") and Medi-Span's Master Drug Database (collectively referred to herein as the "publishers").
- 63. In periodically announcing the AWP for each drug, the publishers publish the prices that are supplied to them by the defendants for their respective drugs. The forward to the 1999 edition of the RedBook stated that "all pricing information is supplied and verified by the products' manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted." A June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the RedBook, stated that it only publishes prices that are faxed directly from the manufacturer. Thus, the AWP generally is not independently determined by the Publishers. Defendants control the prices listed as the AWPs for each drug.
  - 64. A system that bases its reimbursement rates for drugs on the published AWP

As if in acknowledgement of the scheme, the forward to the 2002 RedBook now reads:

All pricing information in RedBook is furnished by manufactures, distributors, and other suppliers. While great care has been taken in compiling the data, we conduct no independent review and therefore cannot guarantee that accuracy of these prices. We continue to regard AWP as one guideline in the pricing equation and to encourage the dissemination of fair, accurate prices by all suppliers.

See 2002 Drug Topics® RedBook, Forward (emphasis added).

is dependent on the honesty of the drug manufacturers.

- 65. Extensive and ongoing federal and Congressional investigations, and settlements as described herein, have revealed that numerous pharmaceutical manufacturers (including certain of the defendants named herein and others not yet named) have engaged in a scheme involving the fraudulent reporting of AWPs for certain prescription pharmaceuticals including but not limited to prescription pharmaceuticals covered by Medicaid.
- 66. Specifically, defendants' AWP Scheme involves the reporting by each defendant of inflated Average Wholesale Prices. The fraudulent reporting of Average Wholesale Prices has the effect of materially misrepresenting the actual prices paid to defendants by providers, in violation of federal and state law.
- AWP for their drugs at any time by forwarding to the Publishers a new and higher AWP. Actual transaction price data -- the amounts actually paid by providers for drugs is not readily publicly available, and defendants keep this information (on which AWPs should have been calculated) highly confidential and secret. This makes it practically impossible to efficiently calculate Medicaid reimbursements based on anything other than AWP. Defendants' concealment of actual price data is one of the many reasons the facts underlying defendants' fraud are peculiarly within defendants' control, and why any applicable statute of limitations should be tolled.
- AWP reported by defendants bears little or no relationship to the prices actually paid by providers, in direct violation of federal and state law. Rather, the reported AWPs for covered drugs were simply fabricated in furtherance of defendants' scheme to generate the profit spread to providers, to increase defendants' profits at the expense of Suffolk and other Medicaid payors, and to control the

market for their products.

69. Defendants' pattern of fraudulent conduct in artificially inflating the AWPs for the Covered Drugs (sometimes referred to herein as the "AWP Scheme") directly and foreseeably causes and has caused Suffolk to overpay substantially for those drugs, given Suffolk's federal and state statutory obligations, of which defendants have, at all times relevant, been aware.

#### B. THE MEDICAID STATUTORY SCHEME

- 70. Medicaid was established by Title XIX of the Federal Social Security Act (the "Act"), 42 U.S.C. 1396, et seq. (the "Medicaid Program"). The Act mandates the establishment of minimum health and safety standards which must be met by providers and suppliers, such as defendants, participating in the Medicaid Program. While participation in Medicaid is voluntary, once a state agrees to participate, as New York has (most recently at New York Social Services Law § 363 et seq, as amended 1998) the state must comply with all federal statutory requirements.
- 71. Among other services and supports, the Medicaid Program pays for certain prescription drugs for those who qualify. Under New York law, N.Y. Social Services Law § 367-a, if such a covered drug is a multiple source prescription drug (generic) or a brand name prescription drug for which no upper limit has been set by the Federal Health Care Financing Administration ("HCFA") (now known as the Centers for Medicare & Medicaid Services (CMS)), then reimbursement under Medicaid is the lower of the providers' usual and customary charge to the general public or the estimated acquisition cost (EAC), of the drug plus a reasonable dispensing fee.
- 72. The dispensers' usual and customary charge is not available anywhere. As a result and, as a practical matter, reimbursement is based entirely upon EAC.
- 73. The EAC is calculated by using the AWP for a drug less a percentage discount. New York's Social Services Law § 367-a(9) expressly defines EAC as "the average

wholesale price of a prescription drug based upon the package size dispensed from, as reported by the prescription drug pricing service used by the department, less ten percent thereof, and updated monthly by the department." The 2002 New York Medicaid Reimbursement Rate is AWP -10% + \$3.50/\$4.50 (dispensing fee). As et forth herein, and confirmed by governmental studies which estimate the average AWP inflation to be in excess of 20%, even this 10% discounted formula results in an overpayment for covered drugs by Medicaid payors such as Suffolk.

- 74. Thus, Suffolk County reimburses providers for Covered Drugs at an amount that is based upon the Covered Drugs' Estimated Acquisition Cost ("EAC") or Average Wholesale Price ("AWP"), as published and reported by the publishers discussed above. As alleged, given that these AWPs are false and inflated, Suffolk has been overcharged.
- Aer 90 MCG and Augmentin Tab 875 ml) had HCFA upper limits established. See Exhibit A hereto. For all other drugs where Medicaid reimbursements were made by Suffolk, such payments were based on AWP and therefore wrongfully and falsely inflated pursuant to the scheme alleged herein. As Exhibit A makes plain, this means that the vast majority of at least Suffolk's top Medicaid reimbursements in 2001 were inflated.
- 76. As stated, there is another aspect to the Medicaid Statutory Scheme implicated here. Under 42 U.S.C. § 1396r-8, in order for a manufacturer of a drug to have its products compensated under Medicaid, the manufacturer must enter into a rebate agreement with the Secretary of Health and Human Services. Pursuant to the rebate agreement, the manufacturer promises to report to Medicaid its "best price" and to pay rebates to Medicaid to ensure that the nation's insurance program for the poor receives the same favorable drug prices offered to other large purchasers of drugs. The statute defines the best price as "the lowest price available from the

manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity." The section also provides that "best price" includes "cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates" and does not include "prices that are merely nominal in amount."

- 77. Upon information and belief, each defendant herein entered into such a rebate agreement with the Secretary of Health and Human Services. In that agreement, each agreed to comply with Section § 1396r-8, and hence:
- (a) Agreed to report its best price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and to make rebates where necessary;
- (b) Agreed that it would determine its best price based upon its average manufacturer's price, calculated as "net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid"; and
- (c) Agreed that the best price would not take into account nominal prices, defined as prices that are less than 10 percent of the average manufacturer's price in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.
- 78. New York Social Services Law § 367-(a)(7)(d) expressly incorporates the rebate requirements of 42 U.S.C. § 1396r-8 and provides that where a manufacturer has entered into a rebate agreement, as outlined above, Medicaid reimbursements shall be made only pursuant to the terms of that rebate agreement.
  - 79. Non-compliance with the best price requirements carries strict penalties. For

example, 42 U.S.C. § 1396r-8(c)(ii) expressly provides that "any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information."

80. Suffolk, like any Medicaid payor, was an intended third party beneficiary of these rebate agreements.

#### C. DEFENDANTS' FRAUDULENT CONDUCT RESPECTING AWP REPORTING AND FAILURE TO REPORT BEST PRICES

#### 1. Artificially Inflating and Fraudulently Reporting AWPs

- 81. Each Defendant Drug Manufacturer provided directly, or caused to be provided (i.e., through WACs that are converted to AWPs) AWPs for each of its drugs to the RedBook, the Blue Book, Medi-Span and other pharmaceutical compendia for Covered Drugs.
- 82. At all times relevant hereto, the defendant drug manufacturers deliberately, routinely and intentionally published or caused to be published AWPs for Covered Drugs that did not reflect the actual prices for the drugs. These inflated prices were reported to cause Medicaid and other governmental programs to overpay for the Covered Drugs. The purpose of artificially inflating the providers' profits was to create an illegal kickback to the providers funded by Medicaid and other government insurers. In other words, the scheme was perpetuated so that providers who purchased the drugs at a low cost would bill patients and their insurers at the inflated AWPs and earn a substantial profit from the "spread" between the real cost and the various AWP-related reimbursement rates. This practice of taking advantage of the difference between the supplier's purchase price and the amount that a provider receives via Medicaid is referred to internally by defendants as "marketing the spread."
- 83. Defendants knew and understood that Medicaid relied on the RedBook and other compendia to determine the AWPs of the covered drugs. Because defendants controlled the

published AWPs, defendants knew and understood that they could manipulate the providers' profits from Medicaid contributors, such as Suffolk.

#### 2. Failure to Report Best Prices

- 84. After execution of the rebate agreement required pursuant to 42 U.S.C. § 1396r-8, each Defendant is required to report its average manufacturer's price in each quarter. Yet, consistent with their artificial inflation of AWPs to publishers, defendants routinely do not report the actual "best price" but, instead, excludes from best price discounts, free samples and other inducements offered to providers to increase use of a drug being reimbursed by governmental entities at a reimbursement rate pegged to AWP.
- 85. The AWP scheme succeeds because precisely because providers are able to obtain drugs at prices significantly below current Medicaid reimbursements. Most manufacturers sell drug products to physicians and other suppliers at a discount from AWP. Sometimes these discounts are substantial.
- 86. The widely available prices available from wholesalers and group purchasing organizations ("GPOs") for covered drugs are considerably less than the AWPs used to establish the Medicaid reimbursement. For most of the high-expenditure or high volume physician-administered drugs, widely available discounts from AWP range at the low end from 13 percent to 34 percent. Recent ongoing federal investigations and settlements involving certain named Defendants reveal much greater discounts sometimes as high as 85%. Providers who have been identified as low-volume billers for certain drugs can also purchase drugs for considerably less than the Medicaid reimbursement.
- 87. Upon information and belief, each of the defendant pharmaceutical companies has also utilized an array of other inducements to stimulate sales of their drugs. These inducements, including educational grants, volume discounts, and rebates or free goods, were

designed to result in a lower net cost to the purchaser while concealing the actual cost price beneath a high invoice price. A product invoiced at \$100 for ten units of a drug item might really only cost the purchaser one-half that amount. If one assumes a subsequent shipment of an additional ten units at no charge, or a "grant," "rebate" or "credit memo" in the amount of \$50, the transaction would truly cost just \$5 per unit net. Through all these "off-invoice" means, drug purchasers were provided the substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price—the price that corresponded to reported AWPs and inflated reimbursement from Medicaid. One example is this from Bayer:

BAYER: "I have been told that our present Kogennate price, \$.66, is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of \$.60 to \$.62 to secure this volume.

- 88. Manufacturers or wholesalers also offer purchasers rebates based on the volume of products purchased not in a single sale but over a period of time. Manufacturers also establish "chargeback" arrangements for purchasers, which result in the AWP overstating what those purchasers pay. Under these arrangements, the purchaser negotiates a price with the manufacturer that is lower than the price the wholesaler charges for the product. The wholesaler provides the product to the purchaser for the lower negotiated price, and the manufacturer then pays the wholesaler the difference between the wholesale price and the negotiated price.
- 89. The defendants also engage in extensive distribution of free samples through their sales and marketing representatives as a means of lowering price. The free samples are used to offset the total cost associated with the drugs, thereby increasing the "spread". Upon information and belief, and as confirmed by certain recent settlements as described herein, defendants specifically instruct providers to bill the government for the free samples, which defendants know is unlawful. The free samples are not taken into account by the drug companies in

calculating the AWP, which in turns inflates the AWP.

- 90. Every free sample of a drug for which a provider bills the government effectively reduces the provider's overall cost for that drug.
- 91. Thus, while federal and state Medicaid statutes law require the defendants to provide quarterly rebates if they charge more than the lowest or "best price" offered to any commercial customer, the defendants routinely fail to do. This is because defendants know that, due to practical problems with ascertaining actual cost charges or street prices, Medicaid administrators routinely determine the allowable payment for a prescription drug based upon the AWP reported by the applicable pharmaceutical manufacturer. *See* New York Social Services Law §367-a(9).
- 92. Recently, two defendants herein, Bayer and GlaxoSmithKline, agreed to pay \$344 million to resolve allegations that they engaged in health care fraud against state programs by failing to report their "best price." The wrongful scheme in which they engaged was known as "lick and stick" wherein they sold re-labeled products to an HMO at deep discounts, and then concealed and avoided their obligations to pay millions of dollars in additional rebates to the Medicaid program.
- 93. At the time of the offenses, Kaiser Permanente Medical Care Program ("Kaiser") was the nation's largest HMO, providing care and treatment to more than 6 million persons, and often purchased drugs directly from drug manufacturers to save on costs for its members, negotiating aggressively for lower prices. Both Bayer and Glaxo provided discounted prices to Kaiser for their drugs and engaged in private labeling for the HMO, affixing different labels to their drug products. These slightly altered labels allowed Bayer and Glaxo to avoid reporting to the federal government, the new low prices given to Kaiser and avoid paying millions

of dollars in additional drug rebates to the Medicaid program. The type of fraud scheme is known as "lick and stick" in reference to the use of a new label on the drug. This is but one example of the ways in which defendants avoid paying proper rebates.

# D. THE DEFENDANT DRUG MANUFACTURERS' USE OF AWP FRAUD TO INCREASE AND MAINTAIN VOLUME AND MARKET SHARE FOR GENERIC AND MULTI-SOURCE DRUGS

- 94. The Defendant Drug Manufactures' AWP fraud is most exacerbated for generic drugs or for brand name drugs, such as Fluoxetine and Albuterol (two of Suffolk's top 2001 Medicaid drugs), for which there are biological or therapeutic equivalents.
- 95. Multi-source drugs or biologicals are also reimbursed on the basis of AWP. New York's Social Services Law defines AWP for multi-source drugs as equal to the lessor of the median AWP of all of the generic forms of the drug or biological, or e the lowest brand name product AWP. Because reimbursement is pegged to the AWP, drug makers act in unison by elevating the AWP for all generic drugs, thereby inflating the amount of the reimbursement that occurs through Medicaid.

#### 96. As stated by one industry consultant:

. . . This situation is more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by substantially inflating their published AWPs. . . . [T]he system allows a retailer to acquire a drug at a low cost \$2.50 per 100 tablets, for example, while relying on a published AWP (\$20.00 or more) for its own pricing. It is not uncommon that the \$25.00 retail price for a generic drug renders a gross profit well above \$20.00 for the retailer. It is also common for the AWP of a generic product to remain stable while the actual selling price declines . . . It is obvious that AWP is not an accurate measure of the prices manufacturers charge. It must also be noted that not all generic products will be priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AW)P. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing decisions and an artificially high AWP provides the retailer with greater profits.

- 97. The raising of an individual defendant's reported AWP for a multi-source drug raises the media AWP at which the generic drug is reimbursed. As a result, the publication and reporting of fraudulent AWPs by defendants for generic drugs squarely fits generic drugs in which the cure of unlawful AWP inflation within the activity complained of herein. Moreover, while any one generic manufacturer can only effect the median generic reimbursement AWP for a product, Defendants can and do create a spread between the median AWP and the actual prices paid by reporting AWPs that are far in excess of the actual wholesale prices while simultaneously maintaining or lowering actual wholesale prices.
- 98. Upon information and belief, generic manufacturers are aware of the AWPs reported by their competitors and of the actual sales price of their generic competitors. Generic drug manufacturers manipulate their own AWPs in order to gain or maintain a competitive advantage in the market for their generic products. Each Defendant generic maker or distributor competes by inflating its AWP and thereby inflating the media AWP. The natural and expected result of the "leap frogging" of increasing AWPs is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs. A few examples are set forth below:

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Baxter	Dextrose	\$ 928.51	\$ 2.25	41,167%
Baxter	Sodium Chloride	\$ 928.51	\$ 1.71	54,199%
Boehrigner	Leucovorin Calcium	\$ 184.40	\$ 2.76	6,581%
B. Braun	Sodium Chloride	\$ 11.33	\$ 1.49	660%
BMS Group*	Etoposide (Vepesid)	\$ 136.49	\$ 34.30	298%

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Dey	Albuterol Sulfate	\$ 30.25	\$ 9.17	230%
Immunex*	Leucovorin Calcium	\$ 137.94	\$ 14.58	846%
Pharmacia*	Etoposide	\$ 157.65	\$ 9.47	1,565%
Sicor Group	Tobramycin Sulfate	\$ 342.19	\$ 6.98	4,802%
Watson	Vancomycin HCL	\$ 70.00	\$ 3.84	1,567%

#### \* Defendants herein.

99. In sum, generic or multi-source drugs are subject to the same fraudulent AWP manipulation as set forth in this Amended Complaint.

#### E. MOTIVATION FOR DEFENDANTS' AWP PRICING SCHEME

- 100. As stated, the purpose and intent of defendants' fraudulent AWP Scheme is to manipulate and thereby increase the amount of reimbursement received by providers of drugs manufactured and sold by defendants.
- 101. Specifically, defendants' AWP Scheme contemplates that (a) defendants will intentionally report falsely and fraudulently inflated AWP prices for these drugs to industry publications; and (b) defendants will actually charge providers amounts for these drugs that are substantially less than the AWP that defendants have fraudulently reported.
- 102. The provider then receives reimbursement from Medicaid, based upon the fraudulently inflated AWP. This circumstance results in a substantial financial incentive to the provider, representing the difference between the inflated AWP-based reimbursement to the provider and the significantly lower direct price charged by defendants to the provider.
  - 103. Defendants refer to the amount received by the provider resulting from the

difference between the fraudulently inflated AWP reimbursement and the price actually paid by the provider as the "spread."

- 104. Each of the defendants has sought to manipulate the market for drugs at issue by inducing providers to prescribe these drugs, rather than competing drugs, because of the higher "spread" resulting from the falsely and fraudulently inflated AWP.
- 105. By participating in the AWP Scheme, defendants seek to influence providers to prescribe the drug with the greatest "spread" between the AWP and the actual direct price paid by the provider to the manufacturer. In fact, defendants have greatly increased their profits by manipulating the AWP to create falsely inflated "spreads", which result in financial incentives to providers to prescribe specific drugs subject to the AWP Scheme.
- 106. The manipulation of AWP at the expense of Medicaid is further revealed when the defendants sell drugs that are not reimbursed by Medicaid. In these circumstances, the drug companies often report accurate AWPs and actually compete with other drug companies on the basis of having a lower AWP than the other company. The company with the lower AWP will urge physicians to consider the cost to the patient when selecting drugs and promote its lower AWP as a selling tool. Thus, when Medicaid is not involved, defendants often ensure that their AWPs are accurate so as to compete for market share based on price.
- 107. Defendants were aware that providers would purchase and utilize products that have the widest spread between the providers' true costs and the reimbursement paid by third parties. All defendants made representations of their AWP for various drugs, which representations were not accurate. In doing so, defendants hoped that providers would view the inflated AWP as a reason for selecting their drug, defendants also knew that this selection would be at the expense governmental payors, like Suffolk

#### V. GOVERNMENT INVESTIGATIONS

Accounting Office ("GAO"), the Office of the Inspector General at the United States Department of HHS ("OIG"), and certain Congressional subcommittees have been investigating defendants and other pharmaceutical manufacturers for questionable practices regarding the industry's calculation of AWPs and for offering illegal incentives to providers.

109. In connection with the investigation of the United States Congress, Congressman Stark wrote most, if not each, of the defendants herein in a letter dated October 31, 2000:

You should by now be aware of Congressional investigations revealing that Abbott has for many years reported and published inflated and misleading data and has engaged in other deceptive business practices. This letter is a call for your company to immediately cease overcharging taxpayers and jeopardizing public health . . . . The price manipulation scheme is executed through Abbott's inflated representations of average wholesale price (AWP) and direct price ("DP") which are utilized by the Medicare and Medicaid Programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is regularly referred to in your industry as "the spread." The evidence amassed by Congress clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims . . . . Based on the evidence collected, Abbott should make arrangements to compensate taxpayers for the financial injury caused to federally funded programs. Any refusal to accept responsibility will most certainly be indicative of the need for Congress to control drug prices. If we cannot rely upon drug companies to make honest and truthful representations about their prices, then Congress will be left with no alternative but to take decisive action to protect the public.

- 110. Congressman Stark made the following five "shocking conclusions":
- First Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.
- Second Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.
- Third Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.
- Fourth Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.
- Fifth Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.
- 111. The Stark materials indicate that defendants employed a number of other financial inducements to stimulate the sales of their drugs at the expense of Medicaid. Such inducements include the practices described herein, *i.e.*, volume discounts, rebates, off-invoice pricing and free goods designed to lower the net cost to the purchaser while concealing the actual cost of the drug from reimbursement officials.
- 112. Congressman Stark released numerous examples of the manipulation of AWP:
- (a) In the 2000 edition of the RedBook, Defendant Bristol reported an AWP of \$1,296.64 for one 20mg/ml, 50ml vial of Vepesid (Etoposide) for injection, while selling

the exact same drug in the same quantity to a GPO for \$70. This represents a spread between Bristol's falsely inflated AWP and the real price of \$1,226.64. Bristol is a defendant herein.

- (b) Effective January 10, 1995, Defendant Glaxo increased the AWP for Zofran by 8.5 percent while simultaneously fully discounting this increase to providers. The net effect of these adjustments was to increase the amount of reimbursements available to providers from Medicaid and others whose reimbursement is based on the AWP. Because the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in the AWP was designed to increase revenue per unit to Glaxo. Absent any other tenable explanation, this adjustment appears to reflect an intent to induce providers to purchase Zofran based on the opportunity to receive increased reimbursement from Medicaid and other third party payors.
- (c) Other examples include Adriamycin, an antibiotic used in cancer treatment and manufactured by Pharmacia, a defendant herein, which had a reported AWP of \$241.36 as of April 2000. The real wholesale price was \$33.43. In 1997, when the reported AWP for this drug was \$946.94, it was being offered to physicians for as low as \$152.00.
- (d) Toposar, also manufactured by Pharmacia, is used to treat testicular and lung cancer. Its AWP as of April 2000 was \$28.38; DOJ found that retailers were buying it for \$1.70.
- (e) Amikacin, used to treat an infection that HIV+ people are susceptible to and manufactured by defendant Abbott, had an AWP of \$54.56. The actual best price was \$6.75. Vancomycin, an antibiotic used to treat intestinal infections and manufactured by Abbott, had an AWP of \$68.77 as of April 2000. DOJ adjusted it to \$8.14.
  - 113. The Department of Health and Human Services, Office of Inspector General

and Department of Justice also are actively investigating the fraudulent pricing practices undergirding this Complaint. Certain of these investigations are discussed in the allegations respecting the individual Defendants, *infra*. In sum, however, the investigations confirm unlawful practices herein described.

114. The Office of Inspector General ("OIG") 2001 review estimated that actual price of brand name prescription drugs was, at the low end, 21.84% below the reported AWP across the board. The OIG estimated that as much as \$1.08 billion nationwide could have been saved for the 200 most frequently reimbursed drugs in Calendar Year 1999, if reimbursement had been based on a greater percentage discount off of AWP, or actual price. Other reports, such as a September 21, 2000 GAO Report had determined that actual prices for top Medicaid/Medicare drugs such as Albuterol (one of Suffolk's top Medicaid pharmacy costs) and Ipratropium bromide were 85% and 75% less than their AWPs. Applying this range of percentages to Suffolk County's Medicaid result in millions of dollars of illegal overcharges since 1995 alone.

115. That same September 21, 2000, GAO report found that:

Widely available discounts for 17 of the physician-billed drugs we examined averaged between 13 percent and 34 percent less than AWP.

For two other physician-billed drugs, Dolasetron mesylate and Leucovorin calcium, average discounts were considerably larger – 65 percent and 86 percent less than AWP

- 116. The report specifically implicated the conduct of defendants Amgen and Johnson & Johnson with respect to at least one of the drugs, paid for by Suffolk as a Medicaid pharmacy cost i.e., epoetin alfal sold as Epogen®.
- 117. In sum, according to the GAO report, the discounts on physician-billed drugs (based on wholesaler and the GPOs' catalogue prices) were notably lower than Medicaid's payment of ten (10) percent below AWP.

- 118. The government investigation confirmed the effectiveness of the AWP scheme. For example, an April 2002 GAO report focusing on sales of a drug in Florida found that Medicaid usage of Vancomycin nearly doubled when Abbott raised the AWP. And when Bayer retained its spread on Whin Rho while other manufacturers did not, its use "skyrocketed."
- 119. This is further demonstrated by comments made in publicly available documents by defendants SmithKline Beecham and TAP:

SMITHKLINE: "In the clinic setting however, since Medicare [like Medicaid] reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP.... Therefore, the spread between the AWP and clinic cost represents a profit to the clinic of \$50.27 for the medication alone. . . . From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regiments."

TAP: "As we have also discussed, Northwest Iowa Urology is very upset about the allowable not going up. I personally met with the doctors to discuss the issue 4/17. The physicians have started using Zoladex but would stop if the allowable issue was taken care of. NWI Urology has 180 patients on Lupron.8"

120. The OIG recently re-admonished pharmaceutical companies to provide an accurate AWP. In its April 2003 report "Compliance Program Guidance for Pharmaceutical Manufacturers," the OIG reminded that "government sets reimbursement with the expectation that the data **provided are complete and accurate**" (emphasis added). The OIG report made it clear that the AWP must be a meaningful figure that is not artificially inflated:

Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices

should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

121. And, the OIG rejected the notion that purposeful AWP manipulation was a

# lawful practice:

The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product. [Emphasis added.]

# VI. ALLEGATIONS PARTICULAR TO SUFFOLK AND THE INDIVIDUAL DEFENDANTS

- 122. Suffolk's own investigations of pricing data confirm that the Average Wholesale Prices reported by defendants for the Covered Drugs reimbursed by Suffolk are fraudulent and inflated. The results of these investigations are set forth in Exhibit A hereto.
- 123. As set forth in detail below for every defendant, Suffolk's research establishes that every reported AWP is false and fraudulently inflated, and that Suffolk was overcharged for every Covered Drug.
- 124. Even these overcharge estimates are understatements because they do not include the defendants' failures to report Best Price as required by federal and state rebate statutes. The impact of these failures on the AWPs at issue and Suffolk's overcharges as a result will be revealed through discovery of defendants' discounting, promotional and rebate practices. When Defendants' failures to report Best Prices are factored in, the spread between reported and true AWPs will be even greater. The facts surrounding Defendants' pricing and promotional activities, which implicate the true Best Price for Covered drugs are uniquely within defendants' control at this time.

## A. ABBOTT LABS

125. At all times relevant hereto, Abbott Labs routinely has reported or caused to be reported, inflated average wholesale prices resulting in overcharges to Suffolk. Based on Suffolk's investigation, in 2001 alone, Abbott reported inflated AWPs for Kaletra Softgel and

# Depakote as follows:

DEPAKOTE TAB 250MG	\$1.04	\$0.77	\$0.27	26%		
DEPAKOTE TAB 500MG	\$1.92	\$1.38	\$0.54	28%		
KALETRA CAP SOFTGEL	\$3.91	\$2.79	\$1.12	29%		

- 126. Upon information and belief, Abbott has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
- 127. Even above estimates do not reveal the full impact of Abbott's fraud because they do not include Abbott's failures to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Abbott's promotional, discounting and pricing practices.
- 128. When Abbott's failure to report Best Price for these drugs is factored in, the spread between reported AWP and true AWP will be even greater. The facts surrounding Abbott's discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within Abbott's control at this time and will be revealed through discovery.
- by at least the United States Department of Justice, the United States Congress, Commonwealth of Massachusetts, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.
- 130. Recently, Abbott agreed to pay \$622 million in criminal and civil penalties for the activities of its Ross Products Unit in defrauding Medicare and Medicaid in a manner

substantively identical to the allegations herein concerning failure to report Best Price. In that proceeding, the U.S. Attorney's Office in the Southern District of Illinois had probed whether Ross Units and its rivals had been using kickbacks to boost sales and defraud government insurers by discounting or giving away products. Providers thereafter would seek government reimbursements at higher prices.

- 131. Abbott, also and notably, was co-venturer with Japan's Takeda Chemical Industries, Ltd. in TAP Pharmaceuticals, which paid \$875 million in a 2001 settlement of allegations that TAP provided free and unreported samples of Lupron, a prostate cancer drug, to physicians with the understanding that the doctors would bill Medicaid and Medicare for reimbursement at an inflated AWP rate.
- 132. At all times relevant hereto, Abbott has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

## B. AGOURON

133. At all times relevant hereto, Agouron routinely has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk. Based on Suffolk's investigation, in 2001 alone, Agouron reported inflated average wholesale prices for Viracept as follows:

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VIRACEPT TAB 250MG	\$2.52	\$1.72	\$0.80	32%

- 134. Upon information and belief, Agouron has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
  - 135. Even the above estimates do not reveal the full impact of Agouron's fraund

because they do not include Agouron's failures to report Best Price as required by federal and satte rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Agouron's promotional, discounting and pricing practices.

- 136. When Agouron's failure to report Best Price for its drugs is factored in, the spread between reported AWP and true AWP will be even greater. The facts surrounding Agouron's discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within Agouron's control at this time and will be revealed through discovery.
- 137. At all times relevant hereto, Agouron has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communication with industry compendia.

# C. AMGEN

138. At all times relevant hereto, Amgen routinely has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk. Based on Suffolk's investigation, in 2001 alone, Amgen reported inflated average wholesale prices for Epogen, Enbrel Kit and Neupogen as follows:

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EPOGEN VIAL 10,000U/ML	\$134.59	\$95.60	\$38.99	29%	
ENBREL KIT 25MG	\$163.33	\$109.74	\$53.59	33%	
NEUPOGEN VIAL 300MCG/ML	\$227.60	\$140.94	\$86.66	38%	

- 139. Upon information and belief, Amgen has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
  - 140. Amgen has utilized other impermissible inducements to stimulate sales of its

drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price.

141. A 1993 OIG Report detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epogen. The report noted that Medicare and Medicare beneficiaries did not receive the benefit of any rebates; all monies remained with the provider. There was no way to provide for any rebates on Medicare claim forms, and Amgen's rebates were not provided until year-end:

[T]he effect of the rebates is that it reduces the actual cost of EPO to a dialysis facility, thus increasing their gross profit. Presently, the rebates represent price reductions which benefit the facilities exclusively.

- 142. By utilizing hidden inducements, Amgen provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.
- 143. Even the estimates and inflated AWPs set forth above are understated because Suffolk's estimates do not take into account Amgen's failures to include Best Price as required by federal and state statute. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Amgen's promotional, discounting and pricing practices.
- 144. When Amgen's failure to report Best Price for the drugs paid for by Suffolk is factored in the spread between reported AWP and true AWP will be even greater. The facts surrounding Amgen's discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within Amgen's control at this time and will be revealed through discovery.
- 145. At all times relevant hereto, Amgen has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

## D. ASTRAZENECA

146. At all times relevant hereto, AstraZeneca routinely has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk. In 2001 alone, based on Suffolk's investigation, AstraZeneca reported inflated average wholesale prices for Prilosec 20 mg tablets and Nexium, as follows:

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NEXIUM CAP 40MG	\$4.14	\$3.02	\$1.12	27%	
PRILOSEC CAP 20MG	\$4.49	\$3.05	\$1.44	32%	
SEROQUEL TAB 100MG	\$2.91	\$2.17	\$0.74	26%	
SEROQUEL TAB 200MG	\$5.48	\$3.96	\$1.52	28%	
SEROQUEL TAB 25MG	\$1.60	\$1.20	\$0.40	25%	

- 147. Upon information and belief, AstraZeneca has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs manufactured by AstraZeneca.
- 148. Even these investigations do not reveal the full impact of AstraZeneca's fraud because Suffolk's estimates do not include AstraZeneca's failures to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of AstraZeneca's promotional and pricing practices.
- 149. When AstraZeneca's failure to report Best Price for these drugs is factored in the spread between reported AWP and true AWP will be even greater. The facts surrounding AstraZeneca's discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within AstraZeneca's control at this time and will be revealed through discovery.

- has been investigated by at least the United States Department of Justice, the Office of the Inspector General of the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex® that an AstraZeneca sales representatives had given the doctor. The indictment alleged that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.
- 151. In June, 2003, AstraZeneca pled guilty and paid \$354.9 million to settle the Zoladex charges. As the U.S. Food and Drug Administration said in it s statement regarding the settlement, "AstraZeneca provided thousands of free samples of Zoladex to physicians knowing that they would charge their patients and insurance programs for the samples."
- 152. Upon information and belief, the Zolodex example is merely one of the ways in which AstraZeneca wrongfully and falsely has inflated its reported AWPs. This unlawful activity, has resulted in excessive overpayments by Suffolk.
- 153. On May 29, 2003, AstraZeneca entered into a Corporate Integrity Agreement ("CIA") with the OIG of the United States Department of Health and Human Services "to promote compliance" "with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. 1320a-7b(f)" ("Federal Health Care Program Requirements"). Contemporaneously AstraZeneca entered into a Settlement Agreement with the United States and various states.

- 154. The CIA covers any individuals who sell or market government reimbursed products on behalf of AstraZeneca; calculate or report prices; and/or include negotiate, implement or report information related to government contracts relating to federal health care programs, including Medicare and the Medicaid Drug Rebate program (codified at 42 U.S.C. 1396r-8 et seq.) The CIA also covers any AstraZeneca employee or agent responsible for "(1) sales and marketing activities for Government Reimbursed Products; (2) the calculation and reporting of prices for federal health care programs, including . . . Medicaid or (3) the negotiation, implementation, and any reporting of information related to government contracts."
- 155. In addition to promising compliance with federal health care program requirements, the CIA requires AstraZeneca to establish a written code of conduct to be agreed to by each covered person that confirms AstraZeneca's "commitment to full compliance with all federal health care program requirements, including its commitment to comply with all government contracting requirements and to market and sell its government reimbursed products in accordance with federal health care program requirements."
- 156. The CIA requires further that AstraZeneca implement policies and procedures that address:
  - (a) the code of conduct described above as well as;
- (b) the calculation and reporting of accurate prices for Government Reimbursed Products to certain entities, including the Centers for Medicare & Medicaid Services ("CMS"), the State Medicaid programs, and the drug price reporting service son which government agencies now rely (etc., First DataBank Inc., the RedBook, etc.) or shall rely in the future;

- (c) the proper calculation and reporting of all data and information reported to CMS and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program, codified at 42. U.S.C. § 1396r-8;
- (d) the proper uses and tracking of drug samples in accordance with all applicable requirements, including, but not limited to, the Prescription Drug Marketing Act, codified in 21 U.S.C. §§ 331, 333 and 352; and
- (e) measures designed to promote marketing and sales practices that conform with all statutes, regulations and requirements applicable to Government Reimbursed Products. The Policies and Procedures shall specify that AstraZeneca shall comply with the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b(1) & (2), and other applicable statutes, regulations or requirements.
- 157. The CIA contemplates monetary penalties for non-compliance, and the retention of an independent review organization, ("IRO"). The IRO shall perform two types of review: (1) a systems review of AstraZeneca's systems, processes, policies and practices relating to the Medicaid Drug Rebate Program ("Medicaid Rebate Systems Review") and (2) a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with AstraZeneca's policies and procedures and Medicaid Drug Rebate Program requirements.
- 158. At all times relevant hereto, AstraZeneca has controlled and set, or caused to be set, the AWPs for its pharmaceutical products through direct communications with industry compendia.

# E. AVENTIS

159. At all times relevant hereto, Aventis routinely has reported or caused to be reported, inflated average wholesale prices, resulting in overcharges to Suffolk.

DOJ documented at least 15 instances where the published AWPs for various dosages of 4 drugs manufactured by Aventis were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 4 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Aventis in the 2001 *RedBook*.

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Helixate FS SOL 1000	\$1.18	\$0.61	\$0.57	48%
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- 161. An OIG report (*see* "Medicare Reimbursement of Prescription Drugs," OEI-03-00-00310, Jan. 2001) further revealed that: (i) the AWP for all immune globulin 5 mg doses listed in the 1997 *RedBook* were inflated by an average spread of 32.21%; (ii) a 10 mg dose of Anzemet had a Medicare Median of \$14.82 and a Catalog Median of \$8.29, resulting in a spread of 78.76%; and (iii) a 20 mg dose of Taxotere had a Medicare Median of \$283.65 and a Catalog Median of \$8.29, resulting in a spread of 18.75%.
- 162. Helixate, listed above as having a 51% spread between reported and actual AWP is one of the covered drugs paid for by Suffolk in 2001.
- 163. Aventis also has been investigated in connection with its pricing activities by the Commerce Committee of the U.S. House of Representatives, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.
  - 164. Upon information and belief, Aventis has engaged in similar inflationary

practices in prior years resulting in comparable damage to Suffolk for all covered drugs manufactured by Aventis.

165. At all times relevant hereto, Aventis has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

# F. BARR

166. At all times relevant hereto, Barr routinely has reported or caused to be reported, inflated AWPs resulting in overcharges to Suffolk. Based on Suffolk's investigation, in 2001 alone, Barr reported inflated AWPs for Fluoxetine as follows:

FLUOXETINE CAP 20MG	\$2.67	\$0.82	\$1.85	69%
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- 167. Upon information and belief, Barr has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
- 168. Even these investigations do not reveal the full impact of Barr's fraud because Suffolk's estimates do not include Barr's failures to report Best Price for Fluoxetine as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Barr's promotional, discounting and pricing practices.
- 169. When Barr's failure to report Best Price for these drugs is factored in, the spread between reported AWP and true AWP will be even greater. The facts surrounding Barr's discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within Barr's control at this time and will be revealed through discovery.

170. At all times relevant hereto, Barr controlled and set, or caused to be set, the reported AWPs for the pharmaceutical products through direct communication with industry compendia.

## G. BAYER

171. Bayer routinely has reported or caused to be reported, inflated AWPs resulting in overcharges to Suffolk. Based on Suffolk's investigation, in 2001 alone, Bayer reported false and inflated AWPs for the drug Cipro as follows:

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CIPRO TAB 500MG		\$5.40	\$3.95	\$1.45	27%
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- 172. Upon information and belief, Bayer has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
- 173. Even these investigations do not reveal the full impact of Bayer's fraud because Suffolk's estimate does not include the Bayer's failures to report the Best Price for Cipro as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Bayer's discounting, promotional and pricing practices.
- 174. When Bayer's failure to report Best Price for these drugs is factored in, the spread between reported and true AWP will be even greater. The facts surrounding Bayer's discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within Bayer's control at this time.
- 175. Bayer's wrongful conduct in this arena is not speculative. In January 2001, Bayer agreed to pay a total of \$14 million to the United States and 45 states to settle allegations

under the federal False Claims Act that the company caused physicians and other health care providers to submit fraudulently inflated reimbursement claims to the state and federally funded Medicaid program. Bayer reached the agreement with the Justice Department, the United States Attorney's Office for the Southern District of Florida in Miami, the Office of Inspector General for the Department of Health and Human Services, and a team of state negotiators from Maine, Nevada, New York and Washington representing the National Association of Medicaid Fraud Control Units.

whistleblower lawsuit in which the government intervened against Bayer, revealed that, beginning in the early 1990's, Bayer falsely inflated the reported drug prices referred to by the industry as the Average Wholesale Price (AWP), the Direct Price, and the Wholesale Acquisition Cost used by State Governments to set the reimbursement rate for the Medicaid program. According to the DOJ's January 23, 2001 press release, by setting an extremely high AWP, and subsequently selling the product to doctors at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit from reimbursement paid to the by the government. The Bayer AWPs at issue in this settlement were Kogenate, Koate-HP, Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases.

177. The Bayer investigation revealed that the practice in which Bayer selectively engaged, commonly referred to by drug manufacturers as "marketing the spread", also had the effect of discouraging market competition from manufacturers that do not inflate AWPs as a way of inducing doctors to purchase their products. In addition to entering into the monetary settlement, Bayer reached a five year agreement with the OIG of HHS that the company's conduct will be monitored by the government under a corporate integrity agreement. Under the compliance

agreement, Bayer will provide the state and federal governments with the average selling prices of its drugs in order to facilitate the government's setting of fair reimbursement rates for the company's products, and potentially, the products of any competitors attempting to take advantage of Bayer's cooperation.

- 178. This Bayer settlement also included settlement of allegations that Bayer knowingly underpaid the Medicaid program for rebates owed by it to the states.
- 179. Additionally, recently Bayer settled certain charges in connection with its efforts to evade paying rebates to states' Medicaid programs which were based on the lowest drug prices they were paying to an HMO, Kaiser Permanente for CIPRO and another Bayer drug, Adalat CC. Bayer is to pay a total of \$275 million to resolve criminal charges and civil liabilities in connection with the fraudulent drug pricing of CIPRO and Adalat. The criminal portion of the global agreement calls for Bayer to plead guilty to charges that it violated the Food, Drug and Cosmetic Act by failing to notify the FDA between August and December 1995, of its production of private label Cipro for Kaiser. Bayer has agreed to pay a criminal fine of \$5.6 million and will admit that it engaged in this conduct with the intent to defraud or mislead. In the civil portion of its global settlement, Bayer will resolve its federal civil False Claims Act liabilities and pay the United States, 49 states, the District of Columbia, and Public Health Service Entities \$251 million in civil damages for losses suffered by the Medicaid program and the Public Health Service entities due to Bayer's failure to report its Kaiser private label price to the government as the true "best price" for its drugs.
- 180. The 2001 Bayer settlement may resolve any claims Suffolk has with respect to the drugs at issue there, it certainly goes no further. To the extent Bayer's recent Best Price Settlement concerns overcharges paid for by Suffolk for Cipro it purports to resolve only one or two

years of such overcharges.

181. At all times relevant hereto, Bayer has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

## H. BERLEX

- 182. At all times relevant hereto, Berlex routinely has reported or caused to be reported, inflated average wholesale prices, resulting in overcharges to Suffolk.
- 183. Based on Suffolk's investigation, in 2001, alone, Berlex reported false and inflated AWPs for Betaseron as follows:

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BETASERON VIAL 0.3MG	\$1,273.00	\$906.98	\$366.02	29%

- 184. Upon information and belief, Berlex has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
- 185. Even Suffolk's investigations do not reveal the full impact of Berlex's fraud because Suffolk's estimates do not include Berlex's failures to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Berlex's discounting, promotional and pricing practices.
- 186. When Berlex's failure to report Best Price for these drugs is factored in, the spread between reported AWP and true AWP will be even greater. The facts surrounding Berlex's discounting and rebate activities, which affect its Best Price, are uniquely within Berlex's control at this time and will be revealed through discovery.
  - 187. At all times relevant hereto, Berlex reported or set, or caused to be set, the

reported AWPs for its pharmaceutical products through direct communication with industry compendia.

## I. BIOGEN

- 188. At all times relevant hereto, Biogen routinely has reported or caused to be reported, inflated average wholesale prices, resulting in overcharges to Suffolk.
- 189. Based on Suffolk's investigation, in 2001 alone, Biogen reported false and inflated AWPs for Avonex as follows:

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AVONEX VL 30MCG	\$1,076.25	\$752.69	\$323.56	30%

- 190. Upon information and belief, Biogen has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
- 191. Even these investigations do not reveal the full impact of Biogen's fraud because Suffolk's estimate does not include Biogen's failures to report its Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Biogen's discounting, promotional and pricing practices.
- 192. When Biogen's failure to report Best Price for these drugs is factored in, the spread between reported AWP and true AWP will be even greater. The facts surrounding Biogen's discounting and rebate activities, which affect its Best Price, are uniquely within Biogen's control at this time and will be revealed through discovery.
- 193. At all times relevant hereto, Biogen has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

# J. BRISTOL-MEYERS SQUIBB

194. Bristol-Meyers Squibb ("BMS")routinely has reported or caused to be reported, inflated average wholesale prices resulting in overcharges to Suffolk. Based on Suffolk's research, in 2001 alone, BMS reported false and inflated average wholesale prices for Buspar, Glucophage, Sustiva, and Pravachol as follows:

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BUSPAR TAB 15	\$2.34	\$1.75	\$0.59	25%
GLUCOPHAGE TAB 1000MG	\$1.61	\$1.18	\$0.43	26%
GLUCOPHAGE TAB 500MG	\$0.78	\$0.58	\$0.20	26%
PLAVIX TAB 75MG	\$4.06	\$2.86	\$1.20	30%
PRAVACHOL TAB 20MG	\$3.08	\$2.09	\$0.99	32%
PRAVACHOL TAB 40MG	\$4.52	\$3.00	\$1.52	34%
SUSTIVA CAP 200MG	\$4.80	\$3.67	\$1.13	24%
ZERIT CAP 40MG	\$5.60	\$4.07	\$1.53	27%

- 195. Upon information and belief, BMS has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
- 196. Even these investigations do not reveal the full impact of BMS' fraud because Suffolk's estimates do not include Bristol-Meyers' failures to report best price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Bristol-Meyers' promotional, discounting and pricing practices.
- 197. When Bristol-Meyers failure to report Best Price for these drugs is factored in, the difference between reported AWP and true AWP will be even greater. The facts surrounding

Bristol-Meyers' discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within Bristol-Meyers' control at this time.

- 198. In connection with its scheme to inflate AWPs, BMS has been investigated by the United California Department of Justice Office of the Attorney General, State of California Department of Justice, Bureau of Medi-Cal Fraud and Elder Abuse, and the U.S. House of Representatives Committee on Commerce.
- 199. These investigations confirm BMS involvement in the wrongful activity undergirding this Complaint. For example, by letter dated February 27, 2001 to BMS, Representative Start outlined numerous examples of illegal practices by BMS. Referring to a letter from Denis Kaszuba, a senior pricing analyst at BMS to Medispan dated August 10, 1992 (BMSAWP/0011247), Rep. Stark noted:

Bristol has control over the AWPs, DPs, and WACs published for its drugs and directs national publishers to change their prices. Bristol directed a national publisher of drug prices to increase all of Bristol's AWPs for oncology drugs by multiplying Bristol's supplied direct prices by a 25% factor rather than the previous 20.5% factor . . .The increasing the AWP created a spread that, in itself, provided a financial kickback to oncologists for prescribing Bristol's cancer drugs.

200. In the same letter, Rep. Stark noted:

The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

201. At all times relevant hereto, Bristol-Myers Squibb has controlled and set the reported AWPs for its pharmaceutical products through direct communications with industry

compendia.

## K. CHIRON

202. At all times relevant hereto, Chiron has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk. Based on Suffolk's investigation, in 2001 alone, Chiron reported inflated average wholesale prices for drug, Tobi as follows:

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				• .
TOBI NEB 300/5 ML	\$2,766.00	\$2,080.97	\$685.03	25%

- 203. Upon information and belief, Chiron has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk.
- 204. Even the above estimates do not reveal the full impact of Chiron's fraud because they do not include Chiron's failures to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Chiron's promotional, discounting and pricing practices.
- 205. When Chiron's failure to report Best Price for these drugs is factored in, the spread between reported AWP and true AWP will be even greater. The facts surrounding Chiron's discounting and rebate activities, which affect the Best Prices for its drugs, and uniquely within Chiron's control at this time and will be revealed through discovery.
- 206. At all times relevant hereto, Chiron has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

# L. ELI LILLY

207. At all times relevant hereto, Eli Lilly routinely has reported or caused to be

reported, inflated AWPs, resulting in overcharges to Suffolk.

208. Based on Suffolk's investigation, in 2001 alone, Eli Lilly reported false and inflated AWPs for Zyprexa and Prozac as follows:

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PROZAC CAP 20MG	\$3.33	\$2.57	\$0.76	23%
PROZAC CAP 40MG	\$6.66	\$5.13	\$1.53	23%
ZYPREXA TAB 10MG	\$9.64	\$6.84	\$2.80	29%
ZYPREXA TAB 15MG	\$14.46	\$10.26	\$4.20	29%
ZYPREXA TAB 2.5MG	\$5.37	\$3.90	\$1.47	27%
ZYPREXA TAB 20MG	\$19.25	\$13.23	\$6.02	31%
ZYPREXA TAB 5MG	\$6.34	\$4.52	\$1.82	29%
ZYPREXA TAB 7.5MG	\$6.76	\$5.10	\$1.66	25%

- 209. Upon information and belief, Ely Lilly has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
- 210. Even these investigations do not reveal the full impact of Eli Lilly's fraud because Suffolk's estimates do not include Eli Lilly's failures to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Eli Lilly's discounting, promotional and pricing practices.
- 211. When Eli Lilly's failure to report Best Price for their drugs is factored in, the spread between reported and true AWP will be even greater. The facts surrounding Eli Lilly's discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within Eli Lilly's control at this and will be revealed through discovery.

212. At all times relevant hereto, Eli Lilly has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

## M. FOREST

213. At all times relevant hereto, Forest has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk. Based on Suffolk's investigation, in 2001 alone, Forest reported inflated average wholesale prices for Celexa as follows:

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CELEVIA TAR SOLG	00.41	A1 77	00.64	2 (2 (
CELEXA TAB 20MG	\$2.41	\$1.77	\$0.64	26%
}	1			

- 214. Upon information and belief, Forest has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk.
- 215. Even the above estimates do not reveal the full impact of Forest's fraud because they do not include Forest's failures to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Forest's promotional, discounting and pricing practices.
- 216. When Forest's failure to report Best Price for these drugs is factored in, the spread between reported AWP and true AWP will be even greater. The facts surrounding Forest's discounting and rebate activities, which affect the Best Prices for its drugs, and uniquely within Forest's control at this time and will be revealed through discovery.
- 217. At all times relevant hereto, Forest has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

# N. FUJISAWA

218. At all times relevant hereto, Fujisawa routinely has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk. For example, based on Suffolk's investigations, Fujisawa reported false and inflated AWPs for Prograf as follows:

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PROGRAF CAP 1MG	\$375.39	\$171.17	\$204.22	54%

- 219. Upon information and belief, Fujisawa has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
- 220. Even these investigations do not reveal the full impact of Fujisawa's fraud because Suffolk's estimates do not include Fujisawa's failures to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Fujisawa's discounting, promotional and pricing practices.
- 221. When Fujisawa's failure to report Best Prices for its drugs is factored in, the difference between reported and true AWP will be even greater. The facts surrounding Fujisawa's discounting and rebate activities, which affect Best Price, are uniquely within Fujisawa's control at this time.
- 222. In connection with its scheme to inflate AWPs, Fujisawa has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.
- 223. At all times relevant hereto, Fujisawa controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry

compendia.

## O. GENENTECH

224. At all times relevant hereto, Genentech routinely has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk. For example, based on Suffolk's investigation, in 2001, alone, Genentech reported false and inflated AWPs for Pulmozyme as follows:

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PULMOZYME SOL 1 M	IG/ML	\$1,439.48	\$1,000.78	\$438.70	30%
				,	

- 225. Even these investigations do not reveal the full impact of Genentech's fraud because Suffolk's estimates do not include Genentech's failures to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Genentech's discounting, promotional and pricing practices.
- 226. When Genentech's failure to report Best Price for their drugs is factored in, the difference between reported and true AWP will be even greater. The facts surrounding Genentech discounting and rebate activities, which affect Best Price, are uniquely within Genentech's control at this time and will be revealed through discovery.
- 227. Upon information and belief, Genentech has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
- 228. At all times relevant hereto, Genentech reported or set, or caused to be set, the reported AWP for its pharmaceutical products through direct communications with industry compendia.

# P. THE GSK DEFENDANTS

229. At all times relevant hereto, the GSK Defendants have reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk. In 2001 alone, based on Suffolk's investigation, GlaxoSmithKline reported false and inflated AWPs for Epivir, Wellbutrin, Lamictal, Paxil, and Serevent Inhaler as follows:

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FLONASE 0.05% NASAL SPRAY	\$62.41	\$43.36	\$19.05	31%	
COMBIVIR TAB	\$10.96	\$7.84	\$3.12	28%	
EPIVIR TAB 150MG	\$5.06	\$3.64	\$1.42	28%	
LAMICTAL TAB 100MG	\$2.91	\$2.20	\$0.71	24%	
ZIAGEN TAB 300MG	\$6.80	\$4.78	\$2.02	30%	
FLOVENT INHALER 110MCG	\$70.58	\$54.82	\$15.76	22%	
SEREVENT INHALER 21MCG	\$84.01	\$64.03	\$19.98	24%	
WELLBUTRIN TAB 150MG	\$1.93	\$1.35	\$0.58	30%	
AUGMENTIN TAB 875-125	\$5.38	\$3.85	\$1.53	28%	
AVANDIA TAB 8MG	\$5.13	\$3.55	\$1.58	31%	
PAXIL TAB 10MG	\$2.70	\$1.94	\$0.76	28%	
PAXIL TAB 20MG	\$2.82	\$1.92	\$0.90	32%	
PAXIL TAB 30MG	\$2.90	\$2.08	\$0.82	28%	
PAXIL TAB 40MG	\$2.95	\$2.20	\$0.75	25%	

- 230. Upon information and belief, GSK has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
  - 231. Even these preliminary investigations do not reveal the full impact of GSK's

fraud because Suffolk's estimates do not include GSK's failures to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of GSK's discounting, promotional and rebate practices.

- 232. When GSK's failure to report Best Price for their drugs is factored in, the difference between reported and true AWP will be even greater. The facts surrounding the GSK defendants' discounting and rebate activities, which affect the Best Price for their drugs, are uniquely within the GSK defendants' control at this and will be revealed through discovery.
- 233. At all time relevant hereto, the GSK defendants reported or set, or caused to be set, the reported AWP for their pharmaceutical products through direct communications with industry compendia.
- 234. In connection with its scheme to inflate AWPs, the GSK Group has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of Nevada, Medicaid Fraud Control Unit.
- 235. These investigations confirm that the GSK Group has engaged in the wrongful conduct at the heart of this Complaint.
- 236. As set forth above, GlaxoSmithKline recently agreed to settle its federal False Claims Act liabilities and pay \$87,600,922 to the United States, 49 states, the District of Columbia and Public Health Service Entities for losses suffered by the Medicaid programs and the Public Health Service entities due to GSK's conduct.
- 237. That proceeding alleged that GSK repackaged and privately labeled Paxil, an antidepressant and Flonase, a nasal spray for Kaiser at discounted prices, but failed to report these

lower prices as "best prices" to the government.

- 238. The GSK Defendants deliberately conceal and have concealed their fraudulent reporting and marketing of the AWP spread. The GSK Defendants routinely require that their customers keep secret the prices they were being charged for GSK Defendants' drugs.
- 239. At all times relevant hereto, the GSK Defendants control and set, or caused to be set, the reported AWPs for their pharmaceutical products through direct communication with industry compendia.
- 240. On April 13, 2003, SmithKline Beecham Corporation, d/b/a/GlaxoSmithKline entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United Dates Department of Health and Human Services "to promote compliance" "with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. ¶ 1320a-7b(f)" ("Federal Health Care Program Requirements"). Contemporaneously GSK entered into a Settlement Agreement with the United States and various states.
- 241. Persons covered by the "CIA" include all employees of the U.S. pharmaceuticals division of GlaxoSmithKline responsible for, *inter alia*, "reporting of pricing information for any products that are reimbursed by federal health care programs, including under the Medicaid Drug Rebate program, codified at 42. U.S.C. ¶ 1396r-8" and "obligations related to government contracts, including the agreements entered with the Department of Health and Human Services under the Medicaid Drug Rebate program and the Drug Pricing program under the Public Health Service (PHS) Act, 42 U.S.C. ¶ 256.
- 242. In addition to promising compliance with federal health care program requirements, the CIA requires GSK to establish a written code of conduct to be agreed to by each

covered person that confirms GSK's "commitment to full compliance with all federal health care program requirements, including its commitment to comply with all government contracting requirements and to market and sell its Government Reimbursed Products in accordance with federal health care program requirements."

- 243. The CIA requires further that GSK implement policies and procedures that address:
  - (a) The code of conduct described above as well as;
- (b) The methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services ("CMS") and/or the state Medicaid programs in connection with the Medicaid Drug Rebate program;
- (c) Promotional practices that conform with all applicable federal health care program requirements, including the Medicaid Drug Rebate program and the Federal anti-kickback statute, codified at 42. U.S.C. ¶ 1302a-7b; and
- (d) The requirements of all government contracts, including those under the Medicaid Drug Pricing program.
- 244. The CIA contemplates monetary penalties for non-compliance, and the retention of an independent review organization, ("IRO"). The IRO shall perform two types of review: (1) a systems review of GSK's systems, processes, policies and practices relating to the Medicaid Drug Rebate program ("Medicaid Rebate Systems Review") and (2) a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with GSK's policies and procedures and Medicaid Drug Rebate program requirements.

# Q. IVAX CORPORATION

245. At all times relevant hereto, upon information and belief, Ivax has reported or

caused to be reported, inflated AWPs, resulting in overcharges to Suffolk for its drugs, including Clozapine.

- 246. Like all other defendants herein, Ivax failed to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Ivax's promotional, discounting and pricing practices.
- 247. The facts surrounding Ivax's discounting and rebate activities, which affect the Best Prices for its drugs, and uniquely within Ivax's control at this time and will be revealed through discovery.
- 248. At all times relevant hereto, Ivax has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

# R. JOHNSON & JOHNSON DEFENDANTS.

- 249. At all times relevant hereto, the Johnson & Johnson defendants (Johnson & Johnson, Janssen, Ortho McNeil, and Ortho Biotech) routinely have reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk.
- 250. As the chart below reveals, based on Suffolk's research, in 2001 alone, Janssen reported false and inflated AWPs for Risperdal, Duragesic, and Aciphex as follows:

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ACIPHEX TAB 20MG	\$3.92	\$3.01	\$0.91	23%		
DURAGESIC DIS 100 MCG/H	\$241.36	\$0.00	\$241.36	100%		
RISPERDAL TAB 0.25MG	\$2.96	\$2.10	\$0.86	29%		
RISPERDAL TAB 0.5MG	\$3.07	\$2.20	\$0.87	28%		

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RISPERDAL TAB 1MG	\$3.17	\$2.39	\$0.78	25%
RISPERDAL TAB 2MG	\$4.87	\$3.74	\$1.13	23%
RISPERDAL TAB 3MG	\$5.94	\$4.63	\$1.31	22%
RISPERDAL TAB 4MG	\$7.68	\$6.14	\$1.54	20%

251. With respect to Ortho McNeil and Ortho Biotach, based on Suffolk's investigation in 2001 alone, Ortho McNeil reported false and inflated AWPs for Ultram, Topamax, and Levaquin as set forth below. Ortho Biotech reported false and inflated AWP for Procrit as follows:

			<del></del>			
TOPAMAX TAB 100MG	\$3.63	\$2.59	\$1.04	29%		
ULTRAM TAB 50MG	\$1.02	\$0.72	\$0.30	29%		
LEVAQUIN TAB 500MG	\$9.30	\$6.95	\$2.35	25%		
PROCRIT VIAL 10000U/ML	\$133.56	\$93.36	\$40.20	30%		
PROCRIT VIAL 20000U/ML	\$267.12	\$185.26	\$81.86	31%		
PROCRIT VIAL 40000U/ML	\$534.24	\$369.47	\$164.77	31%		

- 252. Upon information and belief, the J&J Defendants have engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
- 253. Even these investigations do not reveal the full impact of the J&J defendants' fraud because Suffolk's estimates do not include the J&J Defendants' failures to report Best Price

as required by federal and state rebate statutes.

- 254. When J&J's failure to report Best Price for their drugs is factored in, the difference between reported and true AWP will be even greater. The facts surrounding J&J's promotional, discounting and rebate activities, which affect Best Price, are uniquely within J&J's control at this and will be revealed through discovery.
- 255. In connection with its scheme to inflate AWPs, the Johnson & Johnson Defendants have been investigated by the General Accounting Office and the Office of the Attorney General for the Commonwealth of Massachusetts.
- 256. The J&J Defendants deliberately conceal and have concealed their fraudulent reporting and marketing of the AWP spread. The J&J Defendants routinely require that their customers keep secret the prices they were being charged for J&J drugs.
- 257. At all times relevant hereto, J&J Defendants have controlled and set, or caused to be set, the reported AWPs for their pharmaceutical products through direct communication with industry compendia.

# S. MEDIMMUNE

258. At all times relevant hereto, Medimmune routinely has reported or caused to be reported false and inflated AWPs resulting in overcharges to Suffolk. Based on Suffolk's investigation, in 2001 alone, Medimmune reported false and inflated AWPs for Synagis as follows:

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SYNAGIS VIAL 100MG	\$1,416.48	\$932.96	\$483.52	34%

## T. MERCK

259. At all times relevant hereto, Merck routinely has reported or caused to be

reported, inflated AWPs, resulting in overcharges to Suffolk. Based on Suffolk's investigation, in 2001 alone, Merck reported false and inflated average wholesale prices for Vioxx, Singulair, Fosamax, Cozar, and Zocor as follows:

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CRIXIVAN TAB 40	\$3.04	\$2.12	\$0.91	30%
FOSAMAX TAB 70MG	\$15.54	\$12.37	\$3.17	20%
SINGULAIR TAB 10MG	\$2.93	\$2.08	\$0.85	29%
VIOXX TAB 25MG	\$2.76	\$1.95	\$0.81	29%
ZOCOR TAB 20MG	\$4.59	\$3.01	\$1.58	35%
ZOCOR TAB 40MG	\$4.59	\$3.06	\$1.53	33%

- 260. Upon information and belief, Merck has engaged in similar inflationary practices in prior years, resulting in comparable damage to Suffolk for all covered drugs.
- 261. Even these investigations do not reveal the full impact of Merck's fraud because the true average wholesale prices for these drugs are even lower than the estimated average retail prices Suffolk has calculated here. Thus, the real spreads between reported and true AWP are even greater than the above chart reveals. In addition, Suffolk's estimates do not include Merck's failures to report Best Price as required by federal and sate rebate statutes. The full impact of their failures on Suffolk's overcharges will be revealed through discovery of Merck's promotional, discounting and pricing practices.
- 262. When Merck's failure to report Best Price for these drugs is factored in, the difference between reported and true AWP will be even greater. The facts surrounding Merck's discounting and rebate activities, which affect the Best Prices of its drugs, are uniquely within

Merck's control at this time.

263. At all times relevant hereto, Merck has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

#### U. NOVARTIS

- 264. At all times relevant hereto, upon information and belief, Novartis has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk for its drugs, including Clorazil.
- 265. Like all other defendants herein, Novartis also fails to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Novartis's promotional, discounting and pricing practices.
- 266. The facts surrounding Novartis's discounting and rebate activities, which affect the Best Prices for its drugs, and uniquely within Novartis's control at this time and will be revealed through discovery.
- 267. At all times relevant hereto, Novartis has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

## V. THE PFIZER DEFENDANTS (PFIZER, AGOURON AND SANOFI-SYNTHELABO, INC.)

268. Pfizer and its subsidiaries (Agouron and Sanofi-Synthelabo, Inc.), collectively referred to herein as the "Pfizer Defendants," routinely has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk. The specific drugs of the Pfizer Defendants for which relief is sought in this case are set forth in Exhibits A and B. Based on

Suffolk's research, in 2001 alone, the Pfizer defendants reported false and inflated AWPs for the drugs at issue as follows:

AMBIEN TAB 10MG	\$2.69	\$2.03	\$0.66	25%
GLUCOTROL XL TAB 10MG	\$0.83	\$0.63	\$0.20	24%
LIPITOR TAB 10MG	\$2.39	\$1.61	\$0.77	32%
LIPITOR TAB 20MG	\$3.64	\$2.42	\$1.22	34%
LIPITOR TAB 40MG	\$3.64	\$2.39	\$1.26	34%
NEURONTIN TAB 300MG	\$1.39	\$0.93	\$0.46	33%
NEURONTIN TAB 400MG	\$1.67	\$1.15	\$0.52	31%
NEURONTIN TAB 600MG	\$2.18	\$1.38	\$0.80	37%
NORVASC TAB 10MG	\$2.17	\$1.47	\$0.70	32%
NORVASC TAB 5MG	\$1.50	\$1.04	\$0.46	31%
ZITHROMAX TAB 250MG	\$7.58	\$5.59	\$1.99	26%
ZOLOFT TAB 100MG	\$2.65	\$1.85	\$0.79	30%
ZOLOFT TAB 50MG	\$2.65	\$1.86	\$0.78	30%
ZYRTEC TAB 10MG	\$210.95	\$132.88	\$78.07	37%
XALATAN 0.005% EYEDROPS	\$53.38	\$39.15	\$14.23	27%
CELEBREX CAP 100MG	\$1.58	\$1.19	\$0.39	25%
CELEBREX CAP 200MG	\$2.76	\$1.93	\$0.83	30%

- 269. Upon information and belief, Pfizer has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
  - 270. Even these investigations do not reveal the full impact of Pfizer's fraud

because Suffolk's estimates do not include Pfizer's failures to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Pfizer's promotional, discounting and rebate practices.

- 271. When Pfizer's failure to report Best Price for these drugs is factored in, the difference between reported ant true AWP will be even greater. The facts surrounding Pfizer's discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within Pfizer's control at this time.
- 272. Pfizer has been investigated by the Office of the Inspector General of the Department of Health and Human Services and has entered into a \$49 million settlement arising from illegal practices with respect to Lipitor. The OIG found that Pfizer has been providing unrestricted educational grants and rebates that were in fact discounts off the purchase price of Lipitor. Pfizer concealed these discounts from states who were entitled to receive the "Best Price" for Lipitor.
- 273. On October 24, 2002, Pfizer entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United Dates Department of Health and Human Services "to promote compliance" "with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. ¶ 1320a-7b(f)" ("Federal Health Care Program Requirements"). Contemporaneously Pfizer entered into a Settlement Agreement with the United States and various states.
- 274. The CIA applies specifically, to, *inter alia*, "all employees of the Pfizer Pharmaceuticals Group whose job responsibilities directly relate to the gathering calculation, verification or reporting of information for purposes of the Medicaid Drug Rebate program" (codified at 42. U.S.C. ¶ 1396r-8 *et seq.*).

- 275. In addition to promising compliance with federal health care program requirements, the CIA requires Pfizer to establish a written code of conduct to be agreed to by each covered person that confirms Pfizer's "commitment to full compliance with all federal health care program requirements, including its commitment to comply with all government contracting requirements and to market and sell its Government Reimbursed Products in accordance with federal health care program requirements."
- 276. The CIA requires further that Pfizer implement policies and procedures that address:
  - (a) The code of conduct described above as well as;
- (b) The methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services ("CMS") and/or the state Medicaid programs in connection with the Medicaid Drug Rebate Program; and
- (c) Promotional practices that conform with all applicable federal health care program requirements, including the Medicaid Drug Rebate Program and the Federal Anti-Kickback Statute, codified at 42. U.S.C. ¶ 1302a-7b.
- 277. The CIA contemplates monetary penalties for non-compliance, and the retention of an independent review organization, ("IRO"). The IRO shall perform two types of review: (1) a systems review of Pfizer's systems, processes, policies and practices relating to the Medicaid Drug Rebate program ("Medicaid Rebate Systems Review") and (2) a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with Pfizer's policies and procedures and Medicaid Drug Rebate program requirements.
  - 278. Pfizer deliberately concealed and has concealed its fraudulent reporting and

marketing of the AWP spread. Pfizer routinely requires that its customers keep secret the prices they were being charged for Pfizer's drugs.

279. At all times relevant hereto, Pfizer has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communication with industry compendia.

#### W. PURDUE

- 280. At all times relevant hereto, upon information and belief, Purdue has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk for its drugs, including Oxycontin®.
- 281. Purdue failed to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Suffolk's overcharges will be revealed through discovery of Purdue's promotional, discounting and pricing practices.
- 282. The facts surrounding Purdue's discounting and rebate activities, which affect the Best Prices for its drugs, and uniquely within Purdue's control at this time and will be revealed through discovery.
- 283. At all times relevant hereto, Purdue has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

#### X. RELIANT PHARM

284. At all times relevant hereto, Reliant has reported or caused to be reported inflated AWPs, resulting in overcharges to Suffolk. For example, based on Suffolk's own investigation, in 2001 alone, Reliant reported false and inflated AWPs for Axid as follows:

····	 			<u> </u>
AXID TAB 150	\$183.57	\$128.23	\$55.34	30%

- 285. Upon information and belief, Reliant Pharm has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all Covered Drugs.
- 286. Even these investigations do not reveal the full impact of Reliant's fraud because Suffolk's estimates do not include Reliant's failures to report Best Price for Axid as required by federal and state rebate statutes. The full impact of Reliant's failures on Suffolk's overcharges will be revealed through discovery of Reliant's promotional and pricing practices.
- 287. When Reliant's failure to report Best Prices for its drugs is factored in, the spread between reported and true AWP and actual cost will be even greater. The facts surrounding Reliant's discounting and rebate activities, which affect the Best Price for its drugs, are uniquely within Reliant's control at this time.
- 288. At all times relevant hereto, Reliant has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communication with industry compendia.

#### Y. SCHERING-PLOUGH

289. At all times relevant hereto, Schering-Plough has reported or caused to be reported, false and inflated AWPs, resulting in overcharges to Suffolk. For example, based on Suffolk's investigation, in 2001 alone, Schering-Plough reported false and inflated AWPs for Claritin as follows:

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CLARITIN TAB 10MG	000.00	041.00		
CLARITIN TAB 10MG	\$92.99	\$61.02	\$31.97	34%

- 290. Even these investigations do not reveal the full impact of Schering-Plough's fraud because Suffolk's estimates do not include Schering's failures to report Best Price as required by federal and state rebate statutes. The full impact of Schering's failures on Suffolk's overcharges will be revealed through discovery of Schering's promotional and pricing practices.
- 291. When Schering-Plough's failure to report Best Prices for its drugs is factored in, the spread between reported and true AWP will be even greater. The facts surrounding Schering's discounting and rebate activities, which affect the Best Price for its drugs, are uniquely within Schering's control at this time.
- 292. Upon information and belief, Schering has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.
- 293. In connection with its practices of inflating AWPs, Schering-Plough has been investigated by the Department of Justice, Texas Attorney General, West Virginia Attorney General, California Attorney General, California Bureau of Medi-Cal Fraud and Elder Abuse, and the Department of Health and Human Services Office of the Inspector General, and the U.S. Attorney for the District of Massachusetts.
- 294. On May 30, 2003, Schering-Plough announced that the U.S. Attorney for the District of Massachusetts had advised that its subsidiary, Schering Corporation, is the subject of a federal grand jury investigation. Schering-Plough is the target of a criminal investigation involving:

  (i) providing remuneration, such as drug samples, to providers to induce the purchase of Schering products for which payment was made through federal health care programs; (ii) selling misbranded

or unapproved drugs; (iii) submitting false wholesale pricing information for its pharmaceutical products to the government; and (iv) destroying evidence and obstructing justice relating to the government's investigation. See Schering-Plough Press Release dated May 30, 2003, located at <a href="http://www.sch-plough.com/news/2003/business/20030530.html">http://www.sch-plough.com/news/2003/business/20030530.html</a>). Moreover, according to Schering-Plough's Form 10-K for the year 2000, this investigation has focused on "whether the AWP set by pharmaceutical companies for certain drugs improperly exceeds the average prices paid by dispensers. . .and other pricing and/or marketing practices."

- 295. Schering took a charge of \$150 million for the fourth quarter of 2002 to reflect its estimate of the likely legal liability from this government probe. The key basis for the government investigation is the federal anti-kickback statute, which prohibits pharmaceutical companies from giving money or other items of value to doctors in exchange for prescribing particular products to Medicaid patients.
- 296. This probe is not a unique experience for Schering. A 2000, Medicaid investigation by the Texas Attorney General had revealed that Schering-Plough, with its subsidiary Warrick, defrauded the State of Texas in the amount of \$14.5 million. Investigators determined that Schering-Plough provided the greatest "spread" amongst the drug companies selling albuterol (one of the drugs paid for by Suffolk) in Texas, and thereby obtained the largest market share for albuterol. Schering-Plough sold a box of albuterol to pharmacies for \$13.50, while it charged the Texas Medicaid program \$40.30, a 200% increase. *See* Cornyn Sues Three Drug Companies for Medicaid Fraud, Press Release by the Office of the Attorney General, State of Texas, September 7, 2000 (www.oag.state.tx.us.gov).
- 297. Schering deliberately concealed and has concealed its fraudulent reporting and marketing of the AWP spread. Schering routinely requires that its customers keep secret the

prices they were being charged for Schering's drugs.

298. At all times relevant hereto, Schering has controlled and set, or caused to set, the reported AWPs for its pharmaceutical products through direct communication with industry compendia.

#### Z. TAP

- 299. At all times relevant hereto, TAP has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk.
- 300. For example, in 2001 alone, based on Suffolk's investigation, TAP reported false and inflated AWPs for Prevacid as follows:

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PREVACID CAP 15MG	\$4.36	\$3.12	\$1.24	28%
PREVACID CAP 30MG	\$4.44	\$3.06	\$1.38	31%

- 301. Even these investigations do not reveal the full impact of the fraud because Suffolk's estimates do not include TAP's failures to report Best Price as required by federal and state rebate statutes. The full impact of TAP's failures on Suffolk's overcharges will be revealed through discovery of TAP's promotional and pricing practices.
- 302. When TAP's failure to report Best Price for these drugs is factored in, the spread between reported AWP and true AWP will be even greater. The facts surrounding TAP's discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within TAP's control at this time.
- 303. Upon information and belief, TAP has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all covered drugs.

- 304. In connection with its scheme to inflate AWPs, TAP has been investigated by the Department of Justice. In addition, on October 13, 2001, the United States Attorney in Boston, Massachusetts announced that TAP Pharmaceutical Products, Inc., a corporation that arose from a partnership between Takeda Chemical Industries Ltd. And Abbott Laboratories, a defendant herein, had agreed to pay \$875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing practices for the drug named Lupron®. As part of the agreement:
- (a) TAP agreed to plead guilty to a conspiracy to violate the Prescription Drug Marketing Act, 21 U.S.C. §§ 331(t) and 333(b), and to pay a \$290 million criminal fine, the largest criminal fine ever in a health care fraud prosecution. The plea agreement between the United States and TAP specifically stated that TAP's criminal conduct caused the Government losses of \$145,000,000;
- (b) TAP agreed to pay the United States Government \$559,483,560 for filing false and fraudulent claims with the Medicare and Medicaid programs as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct;
- (c) TAP agreed to pay the fifty states and the District of Columbia \$25,516,440 for filing false and fraudulent claims with the States, as a result of TAP's drug pricing and marketing misconduct, and for TAP's failure to provide state Medicaid programs TAP's best price for Lupron®, as required by law;
- (d) TAP agreed to comply with the terms of a sweeping Corporate Integrity Agreement that, among other things, significantly changes the manner in which TAP supervises its marketing and sales staff and ensures that TAP will report to the Medicare and Medicaid programs the true average sale price for drugs reimbursed by those programs;

- (e) Abbott and Takeda (the TAP co-venturers) agreed to cooperate fully with the ongoing government investigation of TAP and its former officers and employees in exchange for the United States declining prosecution of Abbott and Takeda for conduct relating to Lupron®; and
- (f) An Indictment was unsealed in the District of Massachusetts against six current or former TAP employees (including an account executive, three District Managers, a National Accounts Manager and the former Vice President of Sales), and a urologist, alleging that they conspired to (i) bill Medicare for free samples of Lupron® and (ii) market Lupron® using the "spread" and the "return to practice" program.
- (g) The TAP defendants have been sued in a separate class action in connection with their fraudulent pricing and marketing practices for Lupron®.
- (h) At a hearing in the criminal matter, which has an extensive record, United Stated District Court Judge William G. Young found:

This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

United States v. TAP Pharm. Prods., Inc., No. CR-01-10354-WGY (D.Mass. Dec. 6, 2001).

305. At all times relevant hereto, TAP has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communications with industry compendia.

#### AA. WARRICK

306. Warrick, a division of Schering-Plough, routinely has reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk. For example, based on Suffolk's

investigations, in 2001, Warrick reported false and inflated AWPs for Albuterol as follows:

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				; ;
ALBUTEROL INHALER 90 MCG	\$21.41	\$10.98	\$10.43	49%

- 307. Even these investigations do not reveal the full impact of the fraud because Suffolk's estimates do not include Warrick's failures to report Best Price as required by federal and state rebate statutes. The full impact of Warrick's failures on Suffolk's overcharges will be revealed through discovery of Warrick's promotional and pricing practices.
- 308. When Warrick's failure to report Best Price for its drugs is factored in, the difference between reported and true AWP will be even greater. The facts surrounding Warrick's promotional, discounting and rebate activities, which affect Best Price, are uniquely within Warrick's control at this time.
- 309. Upon information and belief, Warrick has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all Covered Drugs.
- 310. At all times relevant hereto, Warrick has controlled and set, or caused to be set, the reported AWPs for its pharmaceutical products through direct communication with industry compendia.

#### BB. WYETH

311. Wyeth routinely reported or caused to be reported, inflated AWPs, resulting in overcharges to Suffolk. As the below chart reveals, based on Suffolk's investigation, in 2001 alone, Wyeth reported false and inflated AWPs for Protonix and Effexor as follows:

EFFEXOR CAP 75MG	\$1.68	\$1.63	\$0.05	3%
PROTONIX TAB 40MG	\$3.30	\$2.45	\$0.85	26%

- 312. Upon information and belief, Warrick has engaged in similar inflationary practices in prior years resulting in comparable damage to Suffolk for all Covered Drugs.
- 313. Even these investigations do not reveal the full impact of the fraud because Suffolk's estimates do not include Wyeth's failures to report Best Price as required by federal and state rebate statutes. The full impact of Wyeth's failures on Suffolk's overcharges will be revealed through discovery of Wyeth's promotional and pricing practices.
- 314. When Wyeth's failure to report Best Price for its drugs is factored in, the difference between reported and true AWP is even greater. The facts surrounding Wyeth's promotional, discounting and rebate activities, which affect Best Price, are uniquely within Wyeth's control at this time.

#### VII. DAMAGES TO SUFFOLK COUNTY

- been increasing dramatically each year. Pursuant to N.Y. Soc. Serv. Law § 368-a, Suffolk County is mandated to contribute 25% of its Medicaid costs ("Medicaid Local Share Costs"). The County is billed a total weekly share by the State of New York, and has no input into what it is billed. Suffolk's 2002 Budget includes \$203.5 million for Medicaid Local Share Costs, and it has requested a \$231 million Medicaid budget for 2003, a 13.5% increase. This increase is typical of what other counties in New York State are expecting next year.
  - 316. One of the primary forces, if not the principal force, behind Suffolk's

increased Medicaid costs are the cost of prescription drugs, whose prices are inflated pursuant to the AWP scheme alleged herein. Suffolk County's Medicaid pharmacy costs have risen 156% between 1995 and 2001. They totaled nearly \$24 million in 2001 alone. Total pharmacy costs for Suffolk County from 1995 to 2001 are as follows:

Year	Total Pharmacy Costs		
1995	\$9.4 million		
1996	\$10.5 million		
1997	\$11.9 million		
1998	\$13.5 million		
1999	\$16.9 million		
2000	\$20.0 million		
2001	\$23.9 million		
January-May 2002	\$10.7 million		

Source: New York State Department of Social Services

- 317. Applying even the most conservative estimates of improper AWP spread, 20-25% (See Exhibit A) to these costs results in millions of dollars in excessive payments by Suffolk for Medicaid pharmacy costs.
- 318. Suffolk County's experience is consistent with the trend nationwide and statewide.
- 319. Expenditures for prescription drugs in the United States is the fastest growing component of health care, and has risen 15% or more per year over the past several years. Spending on prescription drugs now accounts for around 10% of total spending on health care in the United

States. The federal government estimates that drug expenditures will rise 13.5% in 2002, an average of 11.7% a year between 2003 and 2007, and an average of 10.3% a year between 2008 and 2011. If these growth rates are sustained, prescription drugs will increase from 10% to nearly 15% of total national health spending by 2011. By comparison, increased spending on physician and hospital services is projected to decline over time, with physician services up 8.2% in 2002, 6.9% per year between 2003 and 2007 and 6% per year between 2008 and 2011. Spending on hospital care is projected to rise 6.7% in 2002, 5.8% per year between 2003 and 2007, and 5.2% per year between 2008 and 2011.

- average 18.1% per year from 1997 to 2000, almost three times the rate of increase of all medical services combined. See NIHCM Foundation Report dated June, 2002, "A Primer Generic Drugs, Patents and the Pharmaceutical Marketplace." In 2002, local, state and the federal governments spent \$20 billion on outpatient prescription drugs for Medicaid beneficiaries, up from \$12.1 billion in 1997. Overall, Medicaid spending on prescription drugs rose from \$4.8 billion in 1990 (6.6% of total Medicaid costs) to \$21 billion in 2000. (107% of total Medicaid costs). This increase has been especially dramatic the past three years, with Medicaid pharmacy costs rising nationwide 19% in 2001, 22% in 2000 and 18% in 1999. This contrasts with a 9% increase in total Medicaid expenditures.
- 321. Thus, this case is brought by Suffolk, *inter alia*, to recover the millions of dollars overpaid as a result of defendants' fraudulent scheme to inflate and maintain the high reimbursement amounts upon which payments made by Suffolk for prescription drugs are based. Defendants' misconduct has unjustly enriched the defendants at the expense of New York's health care system, and ultimately, all New York residents, consumers and taxpayers. In particular, the

AWP Scheme directly has cost the County of Suffolk millions of dollars in excess Medicaid pharmacy costs.

#### VIII. FRAUDULENT CONCEALMENT

- 322. Each Defendant concealed its fraudulent conduct from Suffolk by controlling the process by which the AWPs for Covered Drugs were inflated and reported falsely to Publishers. Defendants prevented Suffolk from knowing what the actual pricing structures for these drugs were, and failed to inform them of the usage of free samples and the provision of other financial incentives to providers and other intermediaries to lower their respective costs for the drugs. Moreover, defendants' fraudulent conduct was of such a nature as to be self-concealing.
- 323. Each Defendant closely guarded its pricing structures, promotional practices and sales figures for their Covered Drugs.
- 324. Each Defendant also concealed its fraudulent conduct by instructing providers and others not to report the prices they paid for the Covered Drugs.
- 325. Each Defendant worked with and motivated provider and intermediary trade associations to halt any investigations or change in the AWP system.
- 326. Each Defendant's efforts to conceal its pricing structures for Covered Drugs is evidence that it knew that its conduct was fraudulent.
- 327. Thus, each Defendant concealed that (i) its AWPs were highly-inflated (and were inflated solely to cause Suffolk to overpay for the Covered Drugs), (ii) it was manipulating the AWPs of the Covered Drugs, and (iii) the AWPs bore no relationship to the prices paid for, or the pricing structure of, the Covered Drugs and brand name drugs as they were sold to providers and others.
- 328. Suffolk, unaware of the true facts about the pricing of the Covered Drugs, and statutorily obligated to a 25% Medicaid contribution has paid and continues to pay for them

based upon and in reliance on the AWPs.

- 329. Suffolk was diligent in pursuing an investigation of the claims asserted in this Complaint. Through no fault of its own, it did not receive inquiry notice nor learn of the factual basis for the claims in this Complaint and the injuries suffered therefrom until recently.
- 330. Any applicable statutes of limitations have been tolled by defendants' knowing and active concealment and denial of the facts alleged herein. Suffolk has been kept in ignorance of vital information essential to knowledge of and the pursuit of these claims, without any fault or lack of diligence on its part. Suffolk could not reasonably have discovered the fraudulent nature of the published AWPs.
- 331. Defendants were and continue to be under a continuing statutorily-imposed duty to disclose to Suffolk the fact that the published AWPs bore and continue to bear no relationship to the prices or pricing structures for Covered Drugs. Because of their knowing, affirmative, and/or active concealment of the fraudulent nature of the published AWPs, defendants are estopped from relying on any statutes of limitations.

#### **CLAIMS FOR RELIEF**

#### **COUNT I**

# VIOLATIONS OF 18 U.S.C. § 1962(C) (AGAINST DEFENDANT DRUG MANUFACTURERS IDENTIFIED HEREIN FOR UNLAWFUL CONDUCT ASSOCIATED WITH MEDICAID COVERED DRUGS)

- 332. The County of Suffolk realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.
- 333. This Count, which alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), is asserted against the defendants.
- 334. The County of Suffolk and Defendants are each "persons" as that term is defined in 18 U.S.C. § 1961(3).
- 335. The following publishers of pharmaceutical industry compendia that periodically publish the AWPs, both in printed and electronic media, for various dosages of drugs are each "persons" as that term is defined in 18 U.S.C. 1961(3): (a) Thomson Medical Economics is a division of Thomson Corporation, a Delaware corporation with its principal place of business located at One Station Place, Stamford, Connecticut, and it is the publisher of the Drug Topics RedBook ("RedBook"); (b) First DataBank, Inc., a Missouri corporation, with its principal place of business at 1111 Bayhill Drive, San Bruno, California, and it is the publisher of drug pricing information including, but not limited to, American Druggist First Databank Annual Directory of Pharmaceuticals and Essential Directory of Pharmaceuticals, commonly referred to as the Blue Book; (c) and Facts & Comparisons, Inc., a division of Lippincott Williams & Wilkins, Inc., a Pennsylvania corporation which acquired all drug information reference products formerly published by Medi-Span, Inc. and which currently make available drug pricing information, including, but not limited to, the Medi-Span Master Drug Data Base. These entities are sometimes collectively referred to herein as "the Publishers."

336. At all relevant times, in violation of 18 U.S.C. § 1962(c), the defendants each conducted the affairs of certain association-in-fact enterprises identified herein as the "Manufacturer-Publisher Enterprises". The affairs of each enterprise affected interstate commerce and, through a pattern of racketeering activity, defendants conducted the affairs of these enterprises.

### The Manufacturer-Publisher Enterprises

For purposes of this claim, certain RICO "enterprises" are associations-in-337. fact consisting of (a) one of the Publishers that reported AWPs and (b) a Defendant Drug Manufacturer, including its directors, employees and agents. These associations-in-fact are sometimes collectively referred to herein as the "Manufacturer-Publisher Enterprises." Each of the Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating pharmaceutical price information, which all too often includes disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the enterprises had a common purpose of perpetuating use of AWPs as a benchmark for reimbursement in the pharmaceutical industry, generally, and specifically for the drugs of that defendant. The manufacturing defendants have this as a purpose because without the AWP scheme, they would not be able to push the spread. The publishers agree to this scheme, because if they did not, the manufacturers could easily revert to the other methods of publishing prices or the publishers would have to independently investigate the AWP at significant expense. The Publishers also have an economic incentive to merely report the AWPs provided to them by the manufacturers, because to do otherwise would require the Publishers to spend money to extensively survey actual sales prices in the market. By simply republishing what is submitted to them by the drug manufacturers, the Publishers save on

expenses and consequently reap greater profits. Thus, each of the Manufacturer-Publisher Enterprises has a common purpose of perpetuating the use of AWPs as a benchmark for reimbursement in the pharmaceutical industry.

because there are contractual relationships, financial ties, and continuing coordination of activities between the Defendant Drug Manufacturer and the specific Publisher that are its associates. As to each of the Manufacturer-Publisher Enterprises, there is a common communication network by which the Defendant Drug Manufacturer and the specific Publisher functioned as a continuing unit. At all relevant times, each of the Manufacturer-Publisher Enterprises was operated by the specific Defendant Drug Manufacturer for criminal purposes, namely, carrying out the AWP scheme.

Drug Manufacturers' AWP Scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme. Each of the publishing manufacturers is aware that the published AWPs are inflated. This awareness comes from the following sources: First, at some point prior to 1992 the publishers in many instances obtained AWPs themselves by survey. From their surveys of those in the distribution chain, they were and are aware that the reported AWPs were not accurate. Second, as various congressional bodies and government agencies reported on AWP inflation, the Publishers did not change or challenge the self-reported AWPs, but continued blindly accepting the requested AWPs. Third, public documents confirm that when the State of Texas began prosecuting Dey Pharmaceuticals for its AWP practices, and when other states began focusing on Dey, the Publishers stopped accepting Dey's reported AWPs and published a different, far lower AWP. They withdrew from the Day enterprise due to

fear that they would be sued if they continued to publish Dey's false AWPs. This prompted a lawsuit by Dey alleging that the Publishers were treating Dey differently than they were treating all other manufacturers.

- 340. The foregoing evidences the Publishers' willing participation in the enterprise; their common purpose in the AWP scheme; and their agreement to a structure wherein the manufacturers made decisions as to what AWPs would be reported. This structure was the basis in which each of the enterprises was structured and its affairs conducted.
- 341. For purposes of this count, the Manufacturer-Publisher Enterprises are identified as follows:
- The Abbott Manufacturer-Publisher Enterprises: (a) The Abbott Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Abbott, and Abbott, including its directors, employees and agents: (1) the Abbott-Thomson Medical Enterprise; (2) the Abbott-First DataBank Enterprise; and (3) the Abbott-Facts & Comparisons Enterprise. Each of the Abbott Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs and (b) deriving profits from those activities. Each of the Abbott Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Abbott and Thomson Medical, Abbott and First DataBank, and Abbott and Facts & Comparisons. As to each of these Abbott Manufacturer-Publisher Enterprises, there is a common communication network by which Abbott and Thomson Medical, Abbott and First DataBank, and Abbott and

Facts & Comparisons share information on a regular basis. As to each of these Abbott-Manufacturer-Publisher Enterprises, Abbott and Thomson Medical, Abbott and First DataBank, and Abbott and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Abbott Manufacturer-Publisher Enterprises was operated and conducted by Abbott for criminal purposes, namely, carrying out the AWP Scheme.

(b) The Agouron Manufacturer-Publisher Enterprise: The Agouron Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Agouron, and Agouron, including its directors, employees and agents: (1) the Agouron-Thomson Medical Enterprise; (2) the Agouron-First DataBank Enterprise; and (3) the Agouron-Facts & Comparisons Enterprise. Each of the Agouron Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Agouron Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Agouron and Thomson Medical, Agouron and First DataBank, and Agouron and Facts & Comparisons. As to each of these Agouron Manufacturer-Publisher Enterprises, Agouron and Thomson Medical, Agouron and First DataBank, and Agouron and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Agouron Manufacturer-Publisher Enterprises was operated and conducted by Agouron for criminal purposes, namely, carrying out the AWP Scheme.

- The Amgen Manufacturer-Publisher Enterprises: The Amgen (c) Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Amgen, and Amgen, including its directors, employees and agents: (1) the Amgen-Thomson Medical Enterprise; (2) the Amgen-First DataBank Enterprise; and (3) the Amgen-Facts & Comparisons Enterprise. Each of the Amgen Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Amgen Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Amgen and Thomson Medical, Amgen and First DataBank, and Amgen and Facts & Comparisons. As to each of these Amgen Manufacturer-Publisher Enterprises, Amgen and Thomson Medical, Amgen and First DataBank, and Amgen and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Amgen Manufacturer-Publisher Enterprises was operated and conducted by Amgen for criminal purposes, namely, carrying out the AWP Scheme.
- (d) The AstraZeneca Manufacturer-Publisher Enterprises: The AstraZeneca Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by AstraZeneca, and AstraZeneca, including its directors, employees and agents: (1) the AstraZeneca-Thomson Medical Enterprise; (2) the AstraZeneca-First DataBank Enterprise; and (3) the AstraZeneca-Facts & Comparisons Enterprise. Each of the AstraZeneca Manufacturer-

Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the AstraZeneca Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between AstraZeneca and Thomson Medical, AstraZeneca and First DataBank, and AstraZeneca and Facts & Comparisons. As to each of these AstraZeneca Manufacturer-Publisher Enterprises, AstraZeneca and Thomson Medical, AstraZeneca and First DataBank, and AstraZeneca and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the AstraZeneca Manufacturer-Publisher Enterprises was operated and conducted by AstraZeneca for criminal purposes, namely, carrying out the AWP Scheme.

(e) The Aventis Group Manufacturer-Publisher Enterprises: The Aventis Group Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Aventis Group, and Aventis Group, including its directors, employees and agents: (1) the Aventis Group-Thomson Medical Enterprise; (2) the Aventis Group-First DataBank Enterprise; and (3) the Aventis Group-Facts & Comparisons Enterprise. Each of the Aventis Group Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Aventis Group Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and

continuing coordination of activities between Aventis Group and Thomson Medical, Aventis Group and First DataBank, and Aventis Group and Facts & Comparisons. As to each of these Aventis Group Manufacturer-Publisher Enterprises, Aventis Group and Thomson Medical, Aventis Group and First DataBank, and Aventis Group and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Aventis Group Manufacturer-Publisher Enterprises was operated and conducted by Aventis Group for criminal purposes, namely, carrying out the AWP Scheme.

(f) The Barr Manufacturer-Publisher Enterprises: The Barr Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Barr, and Barr, including its directors, employees and agents: (1) the Barr-Thomson Medical Enterprise; (2) the Barr-First DataBank Enterprise; and (3) the Barr-Facts & Comparisons Enterprise. Each of the Barr Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Barr Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Barr and Thomson Medical, Barr and First DataBank, and Barr and Facts & Comparisons. As to each of these Barr Manufacturer-Publisher Enterprises, Barr and Thomson Medical, Barr and First DataBank, and Barr and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Barr Manufacturer-Publisher Enterprises was operated and conducted by Barr for criminal purposes, namely, carrying out the AWP Scheme.

- (g) The Bayer Manufacturer-Publisher Enterprises: The Bayer Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Bayer, and Bayer, including its directors, employees and agents: (1) the Bayer-Thomson Medical Enterprise; (2) the Bayer-First DataBank Enterprise; and (3) the Bayer-Facts & Comparisons Enterprise. Each of the Bayer Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Baver Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Bayer and Thomson Medical, Bayer and First DataBank, and Bayer and Facts & Comparisons. As to each of these Bayer Manufacturer-Publisher Enterprises, Bayer and Thomson Medical, Bayer and First DataBank, and Bayer and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Bayer Manufacturer-Publisher Enterprises was operated and conducted by Bayer for criminal purposes, namely, carrying out the AWP Scheme.
- (h) The Berlex Manufacturer-Publisher Enterprises: The Berlex Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Berlex, and Berlex, including its directors, employees and agents: (1) the Berlex-Thomson Medical Enterprise; (2) the Berlex-First DataBank Enterprise; and (3) the Berlex-Facts & Comparisons Enterprise. Each of the Berlex Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated

for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Berlex Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Berlex and Thomson Medical, Berlex and First DataBank, and Berlex and Facts & Comparisons. As to each of these Berlex Manufacturer-Publisher Enterprises, Berlex and Thomson Medical, Berlex and First DataBank, and Berlex and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Berlex Manufacturer-Publisher Enterprises was operated and conducted by Berlex for criminal purposes, namely, carrying out the AWP Scheme.

Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Biogen, and Biogen, including its directors, employees and agents: (1) the Biogen-Thomson Medical Enterprise; (2) the Biogen-First DataBank Enterprise; and (3) the Biogen-Facts & Comparisons Enterprise. Each of the Biogen Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Biogen Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Biogen and Thomson Medical, Biogen and First DataBank, and Biogen and Thomson Medical, Biogen and First DataBank, and Biogen and Thomson Medical, Biogen and First DataBank, and Biogen and Facts & Comparisons functioned as continuing but separate

units. At all relevant times, each of the Biogen Manufacturer-Publisher Enterprises was operated and conducted by Biogen for criminal purposes, namely, carrying out the AWP Scheme.

- The BMS Manufacturer-Publisher Enterprises: (i) The BMS Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by BMS, and BMS, including its directors, employees and agents: (1) the BMS-Thomson Medical Enterprise; (2) the BMS-First DataBank Enterprise; and (3) the BMS-Facts & Comparisons Enterprise. Each of the BMS Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the BMS Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between BMS and Thomson Medical, BMS and First DataBank, and BMS and Facts & Comparisons. As to each of these BMS Manufacturer-Publisher Enterprises, BMS and Thomson Medical, BMS and First DataBank, and BMS and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the BMS Manufacturer-Publisher Enterprises was operated and conducted by BMS for criminal purposes, namely, carrying out the AWP Scheme.
- (k) The Chiron Manufacturer-Publisher Enterprises: The Chiron Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Chiron, and Chiron, including its directors, employees and agents: (1) the Chiron-Thomson Medical Enterprise; (2) the Chiron-First DataBank Enterprise; and (3) the Chiron-Facts & Comparisons Enterprise.

Each of the Chiron Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Chiron Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Chiron and Thomson Medical, Chiron and First DataBank, and Chiron and Facts & Comparisons. As to each of these Chiron Manufacturer-Publisher Enterprises, Chiron and Thomson Medical, Chiron and First DataBank, and Chiron and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Chiron Manufacturer-Publisher Enterprises was operated and conducted by Chiron for criminal purposes, namely, carrying out the AWP Scheme.

(I) The Eli Lilly Manufacturer-Publisher Enterprises: The Eli Lilly Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Eli Lilly, and Eli Lilly, including its directors, employees and agents: (1) the Eli Lilly-Thomson Medical Enterprise; (2) the Eli Lilly-First DataBank Enterprise; and (3) the Eli Lilly-Facts & Comparisons Enterprise. Each of the Eli Lilly Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Eli Lilly Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Eli Lilly and Thomson Medical, Eli Lilly and First DataBank, and Eli Lilly and Facts & Comparisons. As to

each of these Eli Lilly Manufacturer-Publisher Enterprises, Eli Lilly and Thomson Medical, Eli Lilly and First DataBank, and Eli Lilly and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Eli Lilly Manufacturer-Publisher Enterprises was operated and conducted by Eli Lilly for criminal purposes, namely, carrying out the AWP Scheme.

- (m) The Forest Manufacturer-Publisher Enterprise: The Forest Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Forest, and Forest, including its directors, employees and agents: (1) the Forest-Thomson Medical Enterprise; (2) the Forest-First DataBank Enterprise; and (3) the Forest-Facts & Comparisons Enterprise. Each of the Forest Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Forest Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Forest and Thomson Medical, Forest and First DataBank, and Forest and Facts & Comparisons. As to each of these Forest Manufacturer-Publisher Enterprises, Forest and Thomson Medical, Forest and First DataBank, and Forest and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Forest Manufacturer-Publisher Enterprises was operated and conducted by Forest for criminal purposes, namely, carrying out the AWP Scheme.
- (n) The Fujisawa Manufacturer-Publisher Enterprises: The Fujisawa Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of

the Publishers that reported the AWPID AWPs that were provided to them by Fujisawa, and Fujisawa, including its directors, employees and agents: (1) the Fujisawa-Thomson Medical Enterprise; (2) the Fujisawa-First DataBank Enterprise; and (3) the Fujisawa-Facts & Comparisons Enterprise. Each of the Fujisawa Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Fujisawa Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Fujisawa and Thomson Medical, Fujisawa and First DataBank, and Fujisawa and Facts & Comparisons. As to each of these Fujisawa Manufacturer-Publisher Enterprises, Fujisawa and Thomson Medical, Fujisawa and First DataBank, and Fujisawa and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Fujisawa Manufacturer-Publisher Enterprises was operated and conducted by Fujisawa for criminal purposes, namely, carrying out the AWP Scheme.

Genentech Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Genentech, and Genentech, including its directors, employees and agents: (1) the Genentech-Thomson Medical Enterprise; (2) the Genentech-First DataBank Enterprise; and (3) the Genentech-Facts & Comparisons Enterprise. Each of the Genentech Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or

otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Genentech Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Genentech and Thomson Medical, Genentech and First DataBank, and Genentech and Facts & Comparisons. As to each of these Genentech Manufacturer-Publisher Enterprises, Genentech and Thomson Medical, Genentech and First DataBank, and Genentech and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Genentech Manufacturer-Publisher Enterprises was operated and conducted by Genentech for criminal purposes, namely, carrying out the AWP Scheme.

(p) The GSK Defendants' Manufacturer-Publisher Enterprises: The GSK Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by the GSK Defendants, including their directors, employees and agents: (1) the GSK Defendants-Thomson Medical Enterprise; (2) the GSK Defendants-First DataBank Enterprise; and (3) the GSK Defendants-Facts & Comparisons Enterprise. Each of the GSK Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the GSK Defendants Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between the GSK Defendants and Thomson Medical, the GSK Defendants Manufacturer-Publisher Enterprises, the GSK Defendants and Thomson Medical, the GSK Defendants

Defendants and First DataBank, and the GSK Defendants and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the GSK Defendants Manufacturer-Publisher Enterprises was operated and conducted by the GSK Defendants for criminal purposes, namely, carrying out the AWP Scheme.

(q) The Ivax Manufacturers-Publisher Enterprises: The Ivax Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Ivax, and Ivax, including its directors, employees and agents: (1) the Ivax-Thomson Medical Enterprise; (2) the Ivax-First DataBank Enterprise; and (3) the Ivax-Facts & Comparisons Enterprise. Each of the Ivax Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Ivax Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Ivax and Thomson Medical, Ivax and First DataBank, and Ivax and Facts & Comparisons. As to each of these Ivax Manufacturer-Publisher Enterprises, Ivax and Thomson Medical, Ivax and First DataBank, and Ivax and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Ivax Manufacturer-Publisher Enterprises was operated and conducted by Ivax for criminal purposes, namely, carrying out the AWP Scheme.

(r) The Johnson & Johnson Defendants<sup>2</sup> Manufacturer-Publisher

Enterprises: The Johnson & Johnson Defendants Manufacturer-Publisher Enterprises are three

<sup>&</sup>lt;sup>2</sup> The Johnson & Johnson Defendants are Johnson & Johnson, Janssen, Ortho McNeil, and Ortho Biotech

separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by the Johnson & Johnson defendants, and the Johnson & Johnson Defendants, including its directors, employees and agents: (1) the Johnson & Johnson-Thomson Medical Enterprise; (2) the Johnson & Johnson-First DataBank Enterprise; and (3) the Johnson & Johnson-Facts & Comparisons Enterprise. Each of the Johnson & Johnson Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs and (b) deriving profits from these activities. Each of the Johnson & Johnson Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Johnson & Johnson and Thomson Medical, Johnson & Johnson and First DataBank, and Johnson & Johnson and Facts & Comparisons. As to each of these Johnson & Johnson Defendants Manufacturer-Publisher Enterprises, Johnson & Johnson Defendants and Thomson Medical, Johnson & Johnson and First DataBank, and Johnson & Johnson Defendants and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Johnson & Johnson Defendants Manufacturer-Publisher Enterprises was operated and conducted by the Johnson & Johnson Defendants for criminal purposes, namely, carrying out the AWP Scheme.

(s) The MedImmune Manufacturer-Publisher Enterprises: The Medimmune Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Medimmune, and Medimmune, including its directors, employees and agents: (1) the Medimmune-Thomson Medical Enterprise; (2) the Medimmune-First DataBank Enterprise; and

- (3) the Medimmune-Facts & Comparisons Enterprise. Each of the Medimmune Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Medimmune Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Medimmune and Thomson Medical, Medimmune and First DataBank, and Medimmune and Facts & Comparisons. As to each of these Medimmune Manufacturer-Publisher Enterprises, Medimmune and Thomson Medical, Medimmune and First DataBank, and Medimmune and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Medimmune Manufacturer-Publisher Enterprises was operated and conducted by Medimmune for criminal purposes, namely, carrying out the AWP Scheme.
- Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Merck & Co., including its directors, employees and agents: (1) the Merck & Co.-Thomson Medical Enterprise; (2) the Merck & Co.-First DataBank Enterprise; and (3) the Merck & Co.-Facts & Comparisons Enterprise. Each of the Merck & Co. Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Merck & Co. Publisher Enterprises has a systemic linkage because there are contractual relationships, financial

ties, and continuing coordination of activities between Merck & Co. and Thomson Medical, Merck & Co. and First DataBank, and Merck & Co., Inc. and Facts & Comparisons. As to each of these, Merck & Co. Publisher Enterprises, Merck & Co. and Thomson Medical, Merck & Co. and First DataBank, and Merck & Co. and Facts & Comparisons function as continuing but separate units. At all relevant times, each of the Merck & Co. Publisher Enterprises was operated and conducted by Merck & Co. for criminal purposes, namely, carrying out the AWP Scheme.

(u) The Novartis Manufacturer-Publisher Enterprises: The Novartis Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Novartis, and Novartis, including its directors, employees and agents: (1) the Novartis-Thomson Medical Enterprise; (2) the Novartis-First DataBank Enterprise; and (3) the Novartis-Facts & Comparisons Enterprise. Each of the Novartis Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Novartis Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Novartis and Thomson Medical, Novartis and First DataBank, and Novartis and Facts & Comparisons. As to each of these Novartis Manufacturer-Publisher Enterprises, Novartis and Thomson Medical, Novartis and First DataBank, and Novartis and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Novartis Manufacturer-Publisher

Enterprises was operated and conducted by Novartis for criminal purposes, namely, carrying out the AWP Scheme.

(v) The Pfizer Defendants' Manufacturer-Publisher Enterprises: The Pfizer Defendants' Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by the Pfizer defendants, and Pfizer, including its directors, employees and agents: (1) the Pfizer defendants-Thomson Medical Enterprise; (2) the Pfizer defendants-First DataBank Enterprise; and (3) the Pfizer-Facts & Comparisons Enterprise. Each of the Pfizer defendants Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Pfizer Defendants' Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Pfizer and Thomson Medical, Pfizer and First DataBank, and Pfizer and Facts & Comparisons. As to each of these Pfizer Defendants' Manufacturer-Publisher Enterprises, the Pfizer Defendants' and each of Thomson Medical, First DataBank, and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Pfizer Defendants' Manufacturer-Publisher Enterprises was operated and conducted by the Pfizer Defendants' for criminal purposes, namely, carrying out the AWP Scheme.

(w) The Pharmacia Manufacturer-Publisher Enterprises: The Pharmacia Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Pharmacia, and

Pharmacia, including its directors, employees and agents: (1) the Pharmacia-Thomson Medical Enterprise; (2) the Pharmacia-First DataBank Enterprise; and (3) the Pharmacia-Facts & Comparisons Enterprise. Each of the Pharmacia Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Pharmacia Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Pharmacia and Thomson Medical, Pharmacia and First DataBank, and Pharmacia and Facts & Comparisons. As to each of these Pharmacia Manufacturer-Publisher Enterprises, Pharmacia and Thomson Medical, Pharmacia and First DataBank, and Pharmacia and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Pharmacia Manufacturer-Publisher Enterprises was operated and conducted by Pharmacia for criminal purposes, namely, carrying out the AWP Scheme.

Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Purdue, and Purdue, including its directors, employees and agents: (1) the Purdue-Thomson Medical Enterprise; (2) the Purdue-First DataBank Enterprise; and (3) the Purdue-Facts & Comparisons Enterprise. Each of the Purdue Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Purdue

Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Purdue and Thomson Medical, Purdue and First DataBank, and Purdue and Facts & Comparisons. As to each of these Purdue Manufacturer-Publisher Enterprises, Purdue and Thomson Medical, Purdue and First DataBank, and Purdue and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Purdue Manufacturer-Publisher Enterprises was operated and conducted by Purdue for criminal purposes, namely, carrying out the AWP Scheme.

The Reliant Manufacturer-Publisher Enterprises: The Reliant **(y)** Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Reliant, and Reliant, including its directors, employees and agents: (1) the Reliant-Thomson Medical Enterprise; (2) the Reliant-First DataBank Enterprise; and (3) the Reliant-Facts & Comparisons Enterprise. Each of the Reliant Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Reliant Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Reliant and Thomson Medical, Reliant and First DataBank, and Reliant and Facts & Comparisons. As to each of these Reliant Manufacturer-Publisher Enterprises, Reliant and Thomson Medical, Reliant and First DataBank, and Reliant and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Reliant Manufacturer-Publisher Enterprises was operated and conducted by Reliant for criminal purposes, namely, carrying out the AWP Scheme.

(z) The Schering-Plough Manufacturer-Publisher Enterprises: Schering-Plough Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Schering-Plough Group, and Schering-Plough Group, including its directors, employees and agents: (1) the Schering-Plough Group-Thomson Medical Enterprise; (2) the Schering-Plough Group-First DataBank Enterprise; and (3) the Schering-Plough Group-Facts & Comparisons Enterprise. Each of the Schering-Plough Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Schering-Plough Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Schering-Plough and Thomson Medical, Schering-Plough and First DataBank, and Schering-Plough and Facts & Comparisons. As to each of these Schering-Plough Manufacturer-Publisher Enterprises, Schering-Plough and Thomson Medical, Schering-Plough and First DataBank, and Schering-Plough and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Schering-Plough Manufacturer-Publisher Enterprises was operated and conducted by Schering-Plough for criminal purposes, namely, carrying out the AWP Scheme.

(aa) The TAP Pharmaceuticals Manufacturer-Publisher Enterprises:

The TAP Pharmaceuticals Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by TAP Pharmaceuticals, and TAP Pharmaceuticals, including its directors, employees and agents:

(1) the TAP Pharmaceuticals-Thomson Medical Enterprise; (2) the TAP Pharmaceuticals-First DataBank Enterprise; and (3) the TAP Pharmaceuticals-Facts & Comparisons Enterprise. Each of the TAP Pharmaceuticals Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the TAP Pharmaceuticals Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between TAP Pharmaceuticals and Thomson Medical, TAP Pharmaceuticals and First DataBank, and TAP Pharmaceuticals and Facts & Comparisons. As to each of these TAP Pharmaceuticals Manufacturer-Publisher Enterprises, TAP Pharmaceuticals and Thomson Medical, TAP Pharmaceuticals and First DataBank, and TAP Pharmaceuticals and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the TAP Pharmaceuticals Manufacturer-Publisher Enterprises was operated and conducted by TAP Pharmaceuticals for criminal purposes, namely, carrying out the AWP Scheme.

(bb) The Warrick Manufacturer-Publisher Enterprises: The Warrick Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Warrick, and Warrick, including its directors, employees and agents: (1) the Warrick-Thomson Medical Enterprise; (2) the Warrick-First DataBank Enterprise; and (3) the Warrick-Facts & Comparisons Enterprise. Each of the Warrick Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and

misleading AWPs, and (b) deriving profits from these activities. Each of the Warrick Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Warrick and Thomson Medical, Warrick and First DataBank, and Warrick and Facts & Comparisons. As to each of these Warrick Manufacturer-Publisher Enterprises, Warrick and Thomson Medical, Warrick and First DataBank, and Warrick and Facts & Comparisons functioned as continuing but separate units. At all relevant times, each of the Warrick Manufacturer-Publisher Enterprises was operated and conducted by Warrick for criminal purposes, namely, carrying out the AWP Scheme.

Manufacturer-Publisher Enterprises are three separate associations-in-fact consisting of each of the Publishers that reported the AWPs that were provided to them by Wyeth, and Wyeth, including its directors, employees and agents: (1) the Wyeth-Thomson Medical Enterprise; (2) the Wyeth-First DataBank Enterprise; and (3) the Wyeth-Facts & Comparisons Enterprise. Each of the Wyeth Manufacturer-Publisher Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWPs, and (b) deriving profits from these activities. Each of the Wyeth Manufacturer-Publisher Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Wyeth and Thomson Medical, Wyeth and First DataBank, and Wyeth and Facts & Comparisons. As to each of these Wyeth Manufacturer-Publisher Enterprises, Wyeth and Thomson Medical, Wyeth and First DataBank, and Wyeth and Thomson Medical, wyeth and First DataBank, and Wyeth and Scontinuing but separate

units. At all relevant times, each of the Wyeth Manufacturer-Publisher Enterprises was operated and conducted by Wyeth for criminal purposes, namely, carrying out the AWP Scheme.

- 342. The defendants' use of the U.S. mails and interstate wire facilities to perpetrate their AWP Schemes involved thousands of communications throughout the relevant time including, *inter alia*:
- (a) Marketing materials about the AWPs for Covered Drugs and the available spread, which were sent to providers located across the country;
- (b) Written representations of the false and inflated AWPs for Covered Drugs as set forth in Exhibit A made to the *RedBook* and similar publications, which were made at least annually, and in many cases, several times during a single year;
- (c) Thousands of written and oral communications discussing, confirming, and forwarding free samples of drugs, for which the defendants understood that the providers would unlawfully seek inflated reimbursement;
- (d) Documents providing information or incentives designed to lessen the prices that providers paid for the drugs, and/or to conceal those prices or the AWP Scheme alleged here;
- (e) Written communications, including checks, documents discussing and relating to grants, payments of consulting fees, debt forgiveness and/or other financial inducements, as detailed herein;
- (f) Written and oral communications with U.S. and state Government agencies and private insurers that fraudulently misrepresented what the AWPs for Covered Drugs were, or that were intended to deter investigations into the AWPs for the Covered Drugs or to forestall changes to reimbursement based on something other than AWPs;

- (g) Written and oral communications with health insurers and patients, inducing payments for Covered Drugs that were made in reliance on AWPs; and
- (h) Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities the wrongful proceeds of the defendants' AWP Scheme.
- (i) In addition to the above-referenced RICO predicate acts, the defendants' respective corporate headquarters have communicated by use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions, in furtherance of the AWP Scheme.

# Conduct of the RICO Enterprises' Affairs and RICO Conspiracy

- 343. During all relevant times, each defendant has exerted control over its particular Publisher Enterprise in violation of Section 1963(c) of RICO, has conducted or participated in the conduct of the affairs of that particular RICO enterprise, directly or indirectly, in the following ways:
- (a) Each defendant has directly controlled the price at which providers purchase its Covered Drugs;
- (b) Each defendant has directly controlled the false and inflated AWPs that are reported in the *RedBook* as set forth in Exhibit A and similar industry publications;
- (c) Each defendant has directly controlled the price at which providers are reimbursed by the Medicaid Program;
- (d) Each defendant has directly controlled the creation and distribution of marketing, sales, and other materials used to inform providers located nationwide of the profit potential of its Covered Drugs;

- (e) Each defendant has directly controlled the marketing and sales scheme to artificially and unlawfully inflate the Medicaid reimbursement rate (and co-payment rate) to induce providers to prescribe Covered Drugs to their patients.
- (f) Each defendant has directly controlled the use and distribution of free samples of its Covered Drugs to providers.
- 344. Each defendant has directly or indirectly controlled the ability of providers to unlawfully seek reimbursement from the Medicaid Program for free samples;
- 345. Each defendant has relied upon its employees and agents to promote the AWP Schemes alleged herein through the U.S. mails, through interstate wire facilities, and through direct contacts with providers; and
- 346. Each defendant has controlled and participated in the affairs of its respective Publisher Enterprise by using a fraudulent scheme to manufacture, market and sell its Covered Drugs through the use of unlawful inducements to providers.
- Complaint had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer. Each of the distribution enterprises also had a consensual decision-making structure because, as described above, each defendant knew it was part of the AWP scheme and the providers played an active role in the affairs of the enterprise. In violation of Section 1962(d) of RICO, each of the defendants and each of the providers that were members of the Distribution Enterprises conspired to conduct the affairs of such enterprises through the pattern of racketeering activity alleged herein. The conspiratorial agreement between the defendants and the providers and their overt acts are described in this Complaint.

# Pattern of Racketeering Activity

348. Each of the defendants has conducted and participated in the affairs of its

respective Publisher Enterprises through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The defendants' pattern of racketeering likely involved thousands, if not hundreds-of-thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their AWP Scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5) in which the defendants intended to defraud Suffolk and other Medicaid payors, the foreseeable and intended victims of the AWP Scheme.

349. The defendants' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWPs for their Covered Drugs, thereby creating a "spread" based on the inflated figure in order to induce providers to prescribe their Covered Drugs to their patients and causing the Medicaid program to pay an artificially-inflated rate of reimbursement for the Covered Drugs. The defendants' AWP Scheme also consisted of providing free samples of the drugs to providers, instructing (or urging) such providers to bill the Medicaid program for these free samples, and providing the providers with other unlawful financial incentives, including kickbacks and bribes, to induce use of the Covered Drugs.

350. The AWP Scheme was calculated and intentionally crafted so as to ensure that the Medicaid Program would be over-billed for the Covered Drugs. In designing and implementing the AWP Scheme, the defendants were at all cognizant of the fact that the entire Medicaid Program and all patients for whom the Covered Drugs are prescribed rely upon the honesty of the defendants in setting the AWP as reported in the *RedBook* and similar publications. Thus, Plaintiff was an intended target and victim of the defendants' AWP Scheme.

- 351. By intentionally and artificially inflating the AWP and thereby affording the providers with unlawful financial inducements to use the Covered Drugs, and by subsequently failing to disclose such practices to the patients from whom reimbursement was sought through the U.S. mails or interstate wire facilities, the defendants engaged in fraudulent, and unlawful conduct constituting a pattern of racketeering activity.
- 352. The defendants' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Suffolk and all Medicaid payors. Each separate use of the U.S. mails and/or interstate wire facilities employed by the defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff. Each of the defendants has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its particular Distribution Enterprise and the Medicaid Enterprise.

# Damages Proximately Caused by the Defendants' AWP Scheme

- 353. The defendants' violations of federal law and their pattern of racketeering activity have directly, proximately and foreseeably caused Suffolk to be injured in its business or property because Suffolk has paid many millions of dollars in inflated reimbursements or other payments for Covered Drugs.
- 354. Defendants sent billing statements through the U.S. mails or by interstate wire facilities and reported AWPs and other information by the same methods in furtherance of their AWP Scheme. As required by federal and state Medicaid law, plaintiff has made inflated reimbursement payments for Covered Drugs based on and/or in reliance on reported and false AWPs.
- 355. Under the provisions of Section 1964(c) of RICO, the defendants are jointly and severally liable to Plaintiff for three times the damages that Plaintiff has sustained,

plus the costs of bringing this suit, including reasonable attorneys' fees.

# COUNT II

# VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. § 1396r-8 FAILURE TO REPORT BEST PRICE

- 356. The County of Suffolk realleges and incorporates the preceding paragraphs as if fully set forth herein.
- 357. Each of the Defendant pharmaceutical companies is a manufacturer of a Covered Drug.
- 358. Pursuant to 42 U.S.C. § 1396r-8, each of the Defendant pharmaceutical companies entered into a rebate agreement with the Medicaid Program under which the Medicaid Program would receive rebates determined in part by "best price," which is defined as "the lowest price available from the manufacturer."
  - 359. In particular, as part of the rebate agreement, each Defendant agreed that:
- (a) It would determine its best price, taking into account discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and would make quarterly rebates where necessary to bring the price down to the actual lowest price offered to any commercial entity;
- (b) It would determine its best price based upon its average manufacturer's price, calculated as "net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid;" and

- (c) It would not take into account nominal prices, defined as prices that are less than 10 percent of the average manufacturer's price in that quarter, so long as the sale of a product at a nominal price was not contingent on any other sale.
- 360. In keeping with their artificial price inflation scheme, each Defendant did not report the actual "best price" or "average manufacturer's price," but instead (i) reported higher prices and (ii) excluded discounts, free samples and other inducements offered to physicians that resulted in lower prices than the prices reported to the Medicaid Program.
- submitted untrue, incomplete, inaccurate, and misleading information used to determine the amount of reimbursement under the Medicaid program. More specifically, each Defendant made or caused claims to be made to the effect that the Medicaid Program was not receiving rebates based upon accurately reported "best price" information, knowing the claims to be rendered false, in whole or in part, falsely reported the prices paid by commercial entities for its products and not accounting for the discounts and other inducements offered to commercial entities. Further, acting with the intent to defraud and in order to obtain authorization to qualify as a provider and to provide specific goods, each Defendant made or caused to be made false statements promising that it would comply with the mandates of 42 U.S.C. §1396r-8.
- 362. Defendants knew, or by virtue of their position, authority or responsibility should have known, of the falsity of their claims, statements or representations.
- 363. Defendants had the authority or responsibility to make such claims, statements and representations, exercised that authority and, as a direct or indirect result, the false statement was made, resulting in a claim for an item when defendants knew or had reason to know that they were not entitled under applicable statutes, regulations, rules, or policies to

Medicaid payment or for the amount of payment requested or claimed.

364. As a result of the defendants' violations of 42 U.S.C. § 1396r-8, Suffolk paid substantially higher prices for reimbursement of the Covered Drugs than it should have, and the Medicaid Program was deprived of its appropriate rebate as a result of defendants' inaccurate reporting of best price.

### **COUNT III**

# VIOLATION OF N.Y. SOCIAL SERVICES LAW § 367(A)(7)(d) <u>FAILURE TO REPORT BEST PRICE</u>

- 365. The County of Suffolk realleges and incorporates the preceding paragraphs as if fully set forth herein.
- 366. Each of the Defendant pharmaceutical companies is a manufacturer of a Covered Drug.
- 367. Pursuant to 42 U.S.C. § 1396r-8, each of the Defendant pharmaceutical companies entered into a rebate agreement with the Medicaid Program under which the Medicaid Program would receive rebates determined in part by "best price," which is defined as "the lowest price available from the manufacturer."
- 368. 42 U.S.C. § 1396r-8 is incorporated by New York State's Medicaid Statute. See New York Social Services Law § 367-(a)(7)(d). New York law expressly provides that each of the defendants who have executed a rebate agreement are to be paid pursuant to that agreement.
- 369. After execution of its agreement, each Defendant was required to report its "best price" in each quarter to the Medicaid Program.
- 370. In keeping with their artificial price inflation scheme, each Defendant did not report the actual "best price" or "average manufacturer's price," but instead (i) reported

higher prices and (ii) excluded discounts, free samples and other inducements offered to physicians that resulted in lower prices than the prices reported to the Medicaid Program.

- 371. Each of the defendants thereby violated N.Y.Soc. Serv. Law § 367-(a)(7)(d) in that they submitted untrue, incomplete, inaccurate, and misleading information used to determine the amount of reimbursement under the Medicaid program. More specifically, each Defendant made or caused claims to be made to the effect that the Medicaid Program was not receiving rebates based upon accurately reported "best price" information, knowing the claims to be rendered false, in whole or in part, falsely reported the prices paid by commercial entities for its products and not accounting for the discounts and other inducements offered to commercial entities. Further, acting with the intent to defraud and in order to obtain authorization to qualify as a provider and to provide specific goods, each Defendant made or caused to be made false statements while promising that it would comply with the mandates of 42 U.S.C. §1396r-8.
- 372. Defendants knew, or by virtue of their position, authority or responsibility should have known, of the falsity of their claims, statements or representations.
- 373. Defendants had the authority or responsibility to make such claims, statements and representations, exercised that authority and, as a direct or indirect result, the false statement was made, resulting in a claim for an item when defendants knew or had reason to know that they were not entitled under applicable statutes, regulations, rules, or policies to Medicaid payment or for the amount of payment requested or claimed.
- 374. As a result of the defendants' violations of 42 U.S.C. § 1396r-8 and New York Social Services Law § 367 et seq., Suffolk paid substantially higher prices for reimbursement of the Covered Drugs than it should have, and the Medicaid Program was deprived of its appropriate rebate as a result of defendants' inaccurate reporting of best price.

### **COUNT IV**

# VIOLATION OF NEW YORK DEPARTMENT OF HEALTH REGULATIONS 18 N.Y.C.R.R. § 515.2(b)(4) and (5)

- 375. The County of Suffolk realleges and incorporates the preceding paragraphs as if fully set forth herein.
- 376. The Regulations of the New York Department of Health 18 N.Y.C.R.R. § 515.2(b)(4) provide that "[c]onversion of a medical assurance payment, or any part of such payment, to a use or benefit other than for the use and benefit intended by the medical assistance program," is an "unacceptable practice" within the New York Medicaid Program.
- 377. The Regulations of the New York Department of Health, 18 N.Y.C.R.R. § 515.2(b)(5) provide that, "[u]nless the discount or reduction in price is disclosed to the client and the department and reflected in a claim," an "Unacceptable Practice" within the New York Medicaid Program is committed by "offering or paying either directly or indirectly any payment (including any kickback, bribe, ... rebate or discount), whether in cash or in kind, in return for purchasing, ... ordering or recommending any medical care, services or supplies for which payment is claimed under the program."
- 378. By engaging in the acts and practices described above, defendants have engaged in and continue to engage in Unacceptable Practices within the New York Medicaid Program as defined at 18 N.Y.C.R.R. § 515.2(b)(4) and (5).

### **COUNT V**

# VIOLATION OF NEW YORK SOCIAL SERVICES LAW § 145-b OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS

- 379. The County of Suffolk realleges and incorporates the preceding paragraphs as if fully set forth herein.
  - 380. New York Social Services Law § 145-b provides that "[i]t shall be

unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for ... supplies furnished ... pursuant to" the Medicaid Program.

- 381. By engaging in the acts and practices described above, defendants have knowingly made false statements and representations or engaged in a fraudulent scheme on behalf of themselves and others, resulting in the overpayment of public funds for defendants' prescription drugs covered by the New York Medicaid Program in violation of Social Services Law § 145-b.
- 382. Specifically, Defendants conduct violated NY Soc. Serv. § 145-b because defendants, and each of them, by means of their false statements and representations and deliberate concealment of material facts attempted to obtain and did in fact obtain payment from public funds for supplies furnished pursuant to this chapter. Defendants made false "statements or representations" under § 145-b(1)(b) because they gave "a [false] report of data which serves as the basis for a claim or a rate of payment."
- 383. Defendants have "attempted to obtain and did obtain payment from public funds for supplies" under § 145-b(1)(c) because they obtained a portion of public funds from which payment was made, and because "public funds [we]re used to reimburse ... an entity from which payment was obtained."
- 384. In the alternative, to the extent the court finds defendants did not obtain payment by virtue of the indirect manner in which they received the public funds that their false statements procure, defendants remain liable because they made a false statement or representation "on behalf of others...to obtain payment from public funds"

# COUNT VI

# BREACH OF CONTRACT

- 385. The County of Suffolk realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.
- 386. As required by 42 U.S.C. § 1396r-8, each Defendant entered into a Rebate Agreement with the Secretary of Health and Human Services ("HHS"). In that agreement, each agreed to comply with Section 1396r-8, and hence:
- (a) Agreed to report its best price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and to make rebates where necessary; and
- (b) Agreed that it would determine its best price based upon its average manufacturer's price, calculated as "net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid;" and
- (c) Agreed that the best price would not take into account nominal prices, defined as prices that are less than 10 percent of the average manufacturer's price in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.
- 387. New York Social Services Law § 367-(a)(7)(D) expressly states that any defendant was has entered into such rebate agreement with HHS, is to be reimbursed pursuant to 42 U.S.C. § 1396r-8.
- 388. Suffolk, like any Medicaid payor, was an intended third-party beneficiary of these rebate agreements.
  - 389. After execution of the rebate agreements, defendants reported their

average manufacturer's price in each quarter to the Medicaid Program.

390. In keeping with their artificial inflation of the AWPs, defendants did not report the actual "best price," for, but not limited to, the drugs identified herein but a significantly greater price that, among other things, excluded discounts and other inducements offered to physicians.

391. Defendants have therefore breached their rebate agreements and caused massive foreseeable damage to the County of Suffolk.

### COUNT VII

# UNFAIR TRADE PRACTICES (Violations of N.Y. Genl. Bus. Law § 349 et seq.)

- 392. The County of Suffolk realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.
- 393. As set forth in particularity herein and in Exhibit A, defendants herein have intentionally and wrongfully inflated the reporting of Average Wholesale Prices for the Covered Drugs.
- 394. As alleged herein, this AWP scheme was designed to increase defendants' sales for their drugs, control the market and decrease consumer choice.
- 395. Defendants intentional wrongful acts caused direct damage to tax paying consumers and Suffolk by wrongfully increasing their Medicaid burden.
- 396. The defendants intentional misconduct has damaged the public and Suffolk County taxpayers.
- 397. New York's Medicaid Statute expressly states, *inter alia*, that "[m]edical assistance for needy persons is hereby declared to be a matter of public concern and a necessity in promoting the public health and welfare." See Social Services Law § 363. Defendants' deceptive acts, as described herein, are in direct contravention of this statutorily articulated public policy. Defendants' practices were consumer-oriented and continue to have a broad impact on consumers and the taxpaying public.
- 398. The County is required by State Law to balance its budget. Every dollar spent on Medicaid, is a dollar that cannot be spent elsewhere.
- 399. Defendants' conduct as alleged in this Complaint constitutes deceptive acts or practices in that:

- (a) Defendants have failed to disclose material facts in the conduct of trade or commerce in that they have not disclosed that the AWP does not reflect the true average wholesale price of the drug products they sell, and that the "best prices" they report are not the actual "best prices" offered to other commercial entities, but are instead inflated in order to drive up the prices paid for medications by the County of Suffolk;
- (b) Defendants have made false or misleading statements of facts concerning the price of goods in that they have lied about the true AWP and "best prices" paid for their medications in order to drive up the prices paid by the County of Suffolk;
- (c) Defendants have knowingly made false representations in a transaction by representing that the AWP is an accurate reflection of the average wholesale price paid for their drugs, and that their reported "best prices" are in fact the "best prices" offered to a commercial entity for their drugs; and
- (d) Defendants have violated state and federal statutes and regulations relating to the sale or lease of goods including, without limitation, the "best price" requirement of the Medicaid statute, the federal mail and wire fraud statutes, 18 U.S.C. §§ 1341 and 1343, the Racketeer Influenced and Corrupt Organizations Act (RICO), particularly 18 U.S.C. § 1962(c) and (d), and New York's Social Services Law, § 367-a, and § 145-b and 18 N.Y.C.R.R. 515.2(b)(4) and (5). These statutory and regulatory violations serve, at minimum, as predicates for the violation of New York's Gen. Bus. Law §349.
- 400. The wrongful conduct alleged in this Complaint occurs and continues to occur in the ordinary course of defendants' business and has caused great harm to the County of Suffolk and the consumers who live there. Suffolk has suffered actual damages because it has had to overpay millions of dollars in Medicaid pharmacy costs as a direct and proximate result of

defendants' deceptive practices.

### COUNT VIII

# **FRAUD**

- 401. The County of Suffolk realleges and incorporates the preceding paragraphs as if fully set forth herein.
- 402. As detailed in this Complaint and Exhibit A, defendants have engaged in actual fraudulent reporting of AWPs and have acted intentionally and with actual malice.
- 403. Defendants have made false representations with knowledge of their falsity, have concealed material facts with the purpose of overcharging Suffolk and Suffolk rightfully has relied upon such misrepresentations. Direct, proximate and foreseeable injury has resulted as a result of such reliance.
- 404. Defendants also had knowledge of facts or intentionally disregarded facts that created a high probability of injury to Suffolk participants, and deliberately proceeded to act in conscious or intentional disregard of, or with indifference to, the high probability of this injury.
- 405. New York's Social Service Law § 366-b expressly provides that "any person who, with intent to defraud, presents for allowance or payment any false or fraudulent claim for furnishing services or merchandise, or who knowingly submits false information for the purpose of obtaining greater compensation than that to which he is legally entitled for furnishing services or merchandise, or knowingly submits false information for the purpose of obtaining authorization of furnishing services or merchandise under this title, shall be guilty of a class A misdemeanor...".
- 406. Defendants' knowing and intentional submission of inflated AWPs to publishers for the express purpose of effectuating the AWP scheme alleged herein constitutes an

intentional fraud pursuant to common law and New York Social Services Law §366-b.

### COUNT IX

# **UNJUST ENRICHMENT**

- 407. The County of Suffolk realleges and incorporates by reference the preceding paragraphs as if fully set forth herein. To the extent the court determines there is no contractual relationship between Suffolk and the defendants, as a direct and proximate result of the unlawful conduct described above, defendants have been and will continue to be unjustly enriched.
- 408. Defendants have benefited from their unlawful acts through the increased sale of Covered Drugs with the greatest spread. It would be inequitable for defendants to retain any of their ill-gotten gains earned as a result of the scheme alleged herein, which gains would not exist but for the overpayments made by Suffolk.
- 409. Suffolk is entitled to an accounting and the establishment of a constructive trust consisting of all overcharges paid by Suffolk for Covered Drugs.

### PRAYER FOR RELIEF

WHEREFORE, plaintiff the County of Suffolk prays for judgment against all defendants as follows:

- 410. Awarding plaintiff actual, statutory, treble and all other available damages for defendants' violation of 18 U.S.C. § 1962(c);
- 411. Adjudging and decreeing that defendants have engaged in the intentional fraudulent conduct alleged herein in violation of N.Y. Soc. Serv. Law §§ 367(a)(7)(d), 366-b and 42 U.S.C. § 1396r-8 and 18 N.Y.C.R.R. 515.2(b)(4) and (5);
- 412. Awarding Suffolk actual, statutory, treble and all other available money damages, including interest, for defendants' violation of N.Y. Gen. Bus. Law § 349 in an amount to be determined at trial;
- 413. Awarding Suffolk actual, statutory, treble and all other available money damages, including interest, for defendants' violation of N.Y. Soc. Serv. Law § 145-b in an amount to be determined at trial;
- 414. Awarding Suffolk actual and compensatory damages in an amount to be determined at trial, with interest, for defendants' breach of contract;
- 415. Awarding Suffolk actual and punitive damages in an amount to be determined at trial, with interest, for defendants' intentional fraud;
- 416. Ordering defendants each to prepare an accounting to determine the amounts defendants have illegally profited at Suffolk's expense, and disgorgement to Suffolk of such monies, with interest;
- 417. Imposing a constructive trust and ordering defendants to pay restitution to Suffolk in the amount Suffolk has been overcharged for Covered Drugs, with interest;
  - 418. Awarding plaintiff the costs of the suit, including costs, reasonable

attorneys' and experts' fees pursuant to 18 U.S.C. § 1964(c), N.Y. Gen. Bus. Law § 349 and N.Y. Soc. Serv. law § 145-b;

419. Such other further and different relief as the Court deems just and proper.

Dated: August 1, 2003.

Paul Sabatino II, Esq. Counsel to the Suffolk County Legislature

Bv:

KIRBY McINERNEY & SQUIRE, LLP

Roger W. Kirby Joanne M. Cicala 830 Third Avenue New York, New York 10022

(212) 371-6600

SPECIAL COUNSEL FOR THE COUNTY OF SUFFOLK

**EXHIBIT A** 

# SUFFOLK MEDICAID OVERCHARGES DRUG BY DRUG

7036	\$0.57		_							+	\$0.74	-				\$366.02 29%	\$323.56 30%	\$0.59
20 22	\$1.38	\$2.79	\$1.72	\$95.60	\$109.74	\$140.94	\$3,02	\$3.05	23.68	\$2.20	\$1.20	\$0.61	\$0.82	\$3.05	0.00	\$6.90	\$752.69	\$1.75
\$1.04	\$1.92	\$3.91	\$2.52	\$134.59	\$163,33	\$227.60	\$4.14	\$4.49	\$5.48	\$2.91	\$1.60	\$1.18	\$2.67	\$5.40	\$1 272 00	\$1,273.00	\$1,076.25	\$2.34
DEPAKOTE TAB 250MG	DEPAKOTE TAB 500MG	KALETRA CAP SOFTGEL	VIRACEPT TAB 250MG	EPOGEN VIAL 10,000U/ML	ENBREL KIT 25MG	NEUPOGEN VIAL 300MCG/ML	NEXIUM CAP 40MG	PRILOSEC CAP 20MG	SEROQUEL TAB 200MG	SEROQUEL TAB 100MG	SEROQUEL TAB 25MG	Helixate FS SOL 1000	FLUOXETINE CAP 20MG	CIPRO TAB 500MG	BETASERON VIAL 0.3MG	AUONITA III AANGO	AVONEX VL 30MCG	BUSPAR TAB 15

ZYPREXA TAB 5MG       \$19.25         ZYPREXA TAB 5MG       \$6.34         ZYPREXA TAB 20MG       \$6.76         PROGRAF CAP IMG       \$2.41         PRIT MOZYME SOL 1 MCAAT       \$375.39			\$1.53 \$2.80 \$4.20 \$1.47 \$6.02 \$1.82 \$1.66 \$0.64	23% 29% 29% 27% 31% 29% 25% 26% 54%
COMBIVIR TAB \$10.96	€ <del>9</del>		\$438.70	30%
	96 \$7.84	4	\$3.12	28%
EPIVIR TAB 150MG		_	47.1¢	70%27

\$62.43	-						\$5.38 \$3.85	\$5.13 \$3.55	\$2.70	\$2.82	\$2.90	\$2.95	\$3.28	\$3.92	\$241.36 \$0.00	\$2.96	\$3.07 \$2.20	\$3.17 \$2.39	\$4.87	\$5.94
FLONASE 0.05% NASAL SPRAY	FLOVENT INHALER 110MCG	LAMICTAL TAB 100MG	SEREVENT INHALER 21MCG	WELLBUTRIN TAB 150MG	ZIAGEN TAB 300MG	AUGMENTIN TAR 875,105	AVANDIA TAB 8MG	PAXII TAB 10MG	DAVII TAB 20MC	FAXIL TAB 20MG	PAXIL TAB 30MG	PAXIL TAB 40MG	CLOZAPINE TAB 100	ACIPHEX TAB 20MG	DURAGESIC DIS 100 MCG/H	RISPERDAL TAB 0.25MG	RISPERDAL TAB 0.5MG	RISPERDAL TAB 1MG	RISPERDAL TAB 2MG	RISPERDAL TAB 3MG

SYNAGIS VIAL 100MG	\$1,416.48	\$932.96	4483 52	3.407	
CRIXIVAN TAB 40	\$3.04	\$2.12	\$0.91	34%	<del></del>
FOSAMAX TAB 70MG	\$15.54	\$12.37	\$3.17	20%	
SINGULAIR TAB 10MG	\$2.93	\$2.08	\$0.85	3/6%	<del></del>
VIOXX TAB 25MG	\$2.76	\$1.95	\$0.81	29%	<del></del>
ZOCOR TAB 20MG	\$4.59	\$3.01	\$1.58	35%	
ZOCOR TAB 40MG	\$4.59	\$3.06	\$1.53	33%	Ţ
TOPAMAX TAB 100MG	\$3.63	\$2.59	\$1.04	29%	Т
ULTRAM TAB 50MG	\$1.02	\$0.72	\$0.30	%60	
LEVAQUIN TAB 500MG	\$9.30	\$6.95	\$2.35	7050	Ţ
PROCRIT VIAL 10000U/ML	\$133.56	\$93.36	\$40.20	23.70	
PROCRIT VIAL 20000U/ML	\$267.12	\$185.26	\$81.86	30%	7
PROCRIT VIAL 40000U/ML	\$534.24	\$369.47	\$164.77	31%	Т
AMBIEN TAB 10MG	82.69	\$2.03	\$104.77	31%	1
GLUCOTROL XL TAB 10MG	\$0.83	\$0.63	\$0.00	25%	<del>-</del>
LIPITOR TAB 10MG	\$7.30	61.61	\$0.20	24%	
LIPITOR TAB 20MG	42.37	31.01	\$0.77	32%	
I IDITOD TAB AONAC	\$3.64	\$2.42	\$1.22	34%	
THION IAB 40MG	\$3.64	\$2.39	\$1.26	34%	
NEURON IIN TAB 300MG	\$1.39	\$0.93	\$0.46	33%	
NEURUN IAB 400MG	\$1.67	\$1.15	\$0.52	31%	
NEURONTIN TAB 600MG	\$2.18	\$1.38	\$0.80	37%	
					_

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NORVASC TAB 5MG	\$1.50	\$1.04	\$0.46	210/
NORVASC TAB 10MG	\$2.17	\$1.47	\$0.70	31%
ZITHROMAX TAB 250MG	\$7.58	\$5.50	\$0.70	32%
ZOLOFT TAB 100MG	\$2.65	\$1.85	61.39	70%
ZOLOFT TAB 50MG	\$9.28	\$1.03	\$0.79	30%
ZYRTEC TAB 10MG	\$210.95	\$132 88	\$0.78	30%
XALATAN 0.005% EYEDROPS	\$53.38	\$39.15	9/0.0/	3/%
CELEBREX CAP 100MG	\$1.58	\$1.75	\$14.23	27%
CELEBREX CAP 200MG	\$2.76	61.13	\$0.39	25%
AXID TAB 150	\$183.57	\$1.93	\$0.83	30%
CLARITIN TAB 10MG	\$92.00	\$120.23	\$55.34	30%
PREVACID CAP 15MG	\$4.36	\$3.12	\$51.97	34%
PREVACID CAP 30MG	\$4.44	\$3.12	47.16	28%
ALBUTEROL INHALER 90 MCG	\$21.41	\$10.00	\$1.58	31%
EFFEXOR CAP 75MG	\$1 68	\$16.70	\$10.43	49%
PROTONIX TAB 40MG	\$3.30	\$1.05	\$0.0\$	3%
	27.14	32.43	\$0.85	76%

EXHIBIT B

<u>TOP SUFFOLK COUNTY 2001 MEDICAID PHARMACY COSTS</u>

		V
ZYPREXA TAB 10MG	ELI LILLY	4.32%
PROCRIT INJ 40000U/M	ORTHO BIOTECH (Johnson & Johnson)	1.75%
PRILOSEC CAP 20MG CR	ASTRAZENECA	1.68%
ZYPREXA TAB 5MG	ELI LILLY	1.63%
CLOZARIL TAB 100MG	NOVARTIS	1.40%
PREVACID CAP 30MG DR	TAP PHARM	1.37%
DEPAKOTE TAB 500MG EC	ABBOTT	1.32%
RISPERDAL TAB 2MG	JANSSEN (Johnson & Johnson)	1.16%
COMBIVIR	Glaxo Wellcome (Now GSK)	1.04%
CELEBREX CAP 200MG	PHARMACIA (Now PFIZER)	0.99%
ZYPREXA TAB 2.5MG	ELI LILLY	0.92%
RISPERDAL TAB 3MG	JANSSEN (Johnson & Johnson)	0.85%
PROZAC CAP 20MG	ELILILLY	0.78%
RISPERDAL TAB 4MG	JANSSEN (Johnson & Johnson)	0.76%
SYNAGIS INJ 100MG	MED IMMUNE	0.75%
NEURONTIN CAP 300MG	PFIZER	0.74%
ZOLOFT TAB 50MG	PFIZER	0.72%
VIOXX TAB 25MG	MERCK	0.68%
ZOCOR TAB 20MG	MERCK	0.68%
AMBIEN TAB 10MG	PFIZER (or SANOFI)	0.66%
LIPITOR TAB 10MG	PFIZER	0.62%
CLOZAPINE TAB 100MG	IVAX	0.58%
ZYPREXA TAB 15MG	ELILILLY	0.57%
ZOLOFT TAB 100MG	PFIZER	0.55%

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DEPAKOTE TAB 250MG	ABBOTT	0.55%
VIRACEPT TAB 250MG	AGOURON (or PFIZER)	0.54%
CLARITIN TAB10MG	SCHERING	0.51%
SEROQUEL 200MG	ASTRAZENECA	0.51%
PAXIL TAB 20MG	GSK Pharmaceuticals	0.49%
LIPITOR TAB 20MG	PFIZER	0.48%
PROCRIT INJ 20000 U/ML	ORTHO BIOTECH (Johnson & Johnson)	0.47%
ZYPREXA TAB 15MG	ELI LILLY	0.47%
AXID CAP 150MG	RELIANT PHARM	0.45%
RISPERDAL TAB 0.5MG	JANSSEN (Johnson & Johnson)	0.45%
SEROQUEL TAB 100MG	ASTRAZENECA	0.43%
AVONEX INJ 33MCG	BIOGEN	0.43%
ZERIT CAP 40MG	BRISTOL MYERS SQUIBB	0.42%
HELIXATE FS SOL 1000	AVENTIS BEHRING (Aventis, S.A.)	0.41%
NORVASC TAB 20MG	PFIZER	0.41%
CELEXA TAB 20MG	FOREST	0.40%
KALETRA CAP SOFTGEL (this is assumption)	ABBOTT	0.38%
ZYPREXA TAB 7.5MG	ELI LILLY	0.38%
DURAGESIC DIS 100MCG/H	JANSSEN (Johnson & Johnson)	0.35%
LEVAQUIN TAB 500MG	ORTHO MCNEIL (Johnson & Johnson)	0.35%
EPIVIR TAB 150MG	GLAXO WELLCOME (Now GSK Pharm)	0.35%
RISPERDAL TAB 0.5MG	JANSSEN (Johnson & Johnson)	0.34%
WELLBUTRIN TAB 150MG SP	GLAXO WELLCOME (Now GSK Pharm)	0.34%
GLUCOPHAGE TAB 500MG	BRISTOL-MYERS SQUIBB	0.31%

PROCRIT INJ 10000ML	ORTHO BIOTECH (Johnson & Johnson)	0.31%
ZYPREXA TAB 20MG	ELI LILLY	0.31%
CRIXIVAN CAP 400MG	MERCK	0.31%
ZYRTEC TAB 10MG	PFIZER	0.30%
PRAVACHOL TAB 40MG	BRISTOL-MYERS SQUIBB	0.29%
NORVASC TAB 5MG	PFIZER	0.29%
SUSTIVA CAP 200MG	BRISTOL-MYERS SQUIBB	0.29%
ENBREL INJ 25MG	IMMUNEX (or AMGEN)	0.29%
PRAVACHOL TAB 20MG	BRISTOL-MYERS SQUIBB	0.27%
CIPRO TAB 500MG	BAYER	0.27%
SEROQUEL TAB 25MG	ASTRAZENECA	0.26%
SINGULAIR TAB 10MG	MERCK	0.26%
BETASERON INJ 0.3MG	BERLEX	0.26%
ALBUTEROL AER 90MCG	WARRICK	0.26%
SEREVENT AER 21MCG	GSK Pharmaceuticals	0.25%
PREVACID CAP 15MG DR	TAP PHARM	0.25%
RISPERDAL TAB 0.25MG	JANSSEN (Johnson & Johnson)	0.25%
TOPAMAX TAB 100MG	ORTHO-McNEIL (Johnson & Johnson)	0.25%
PAXIL TAB 30MG	GSK Pharmaceuticals	0.25%
ZOCOR TAB 40MG	MERCK (from Pfizer)	0.24%
NEURONTIN CAP 400MG	PFIZER	0.24%
PRILOSEC CAP 20MG CR	ASTRAZENECA	0.24%
AUGMENTIN TAB 875MG4	GSK PHARM	0.23%
NEURONTIN TAB 600MG	PFIZER	0.23%
LONASE SPR 0.05%	GSK PHARM	0.23%
AXIL TAB 10MG	GSK PHARM	0.23%
LOVENT AER 110MCG/A	GLAXO WELLCOME (Now GSK)	0.23%
MMUNE GLOBU INJ 10%	TBD	0.23%

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ACIPHEX TAB 20MG	JANSSEN (Johnson & Johnson)	0.22%
FLUOXETINE CAP 20MG	BARR LABORATORIES	0.22%
CELEBREX CAP 100MG	PHARMACIA (Now Pfizer)	0.22%
GLUCOPHAGE TAB 1000MG	BRISTOL-MYERS SQUIBB	0.22%
PROGRAF CAP 1MG	FUJISAWA	0.22%
PROZAC CAP 40MG	ELI LILLY	0.21%
OXYCONTIN TAB 40MG CR	PURDUE PHARMA	0.21%
ZITHROMAX TAB 250MG	PFIZER	0.21%
LIPITOR TAB 40MG	PFIZER	0.21%
GLUCOTROL XL TAB 10MG	PFIZER	0.21%
AVANDIA TAB 8MG	GSK PHARM	0.20%
ZIAGEN TAB 300mg	GLAXO WELLCOME (Now GSK)	0.20%
XALATAN SOL 0.005%	PHARMACIA CORP. (Now PFIZER)	0.20%
EFFEXOR XR CAP 75MG	WYETH-AYERST	0.20%
PAXIL TAB 40MG	GSK PHARM	0.20%
PULMOZYME SOL 1MG/ML	GENENTECH	0.20%
ULTRAM TAB 50MG	ORTHO-McNEIL PHARM (Johnson & Johnson)	0.20%
BUSPAR TAB 15MG	BRISTOL MYERS SQUIBB	0.20%
TOBI NEB 300/5ML	CHIRON CORP.	0.20%
NEXIUM CAP 40MG	ASTRA ZENECA	0.19%
LAMICTAL TAB 100MG	GLAXO WELLCOME (Now GSK)	0.19%
PROTONIX TAB 40MG	WYETH-AYERST	0.19%
EPOGEN INJ 10000/ML	AMGEN INC.	0.19%
DXYCONTIN TAB 80MG	PURDUE PHARMA	0.19%
OSAMAX TAB 70MG	MERCK	0.19%
PLAVIX TAB 75MG	BRISTOL MYERS SQUIBB (or SANOFI)	0.19%

NORVASC TAB 5MG	PFIZER	0.19%
NEUPOGEN INJ 300ML	AMGEN INC.	0.18%